CHAPTER 8 - INVESTIGATIONS

8.1 - Investigations and Inspections

8.1.1 – Background – What is an investigation?

An *investigation* is an information-gathering activity conducted for several reasons and this definition applies across ORA programs. The purpose of an investigation is to determine and document facts concerning an issue to inform the agency in making sound decisions. Used informally, *investigation* can apply to a very general activity. It may refer to a response to a more formal request for specific information. Information obtained during an investigation may lead to other operations such as sample collections or inspections.

This chapter contains specific information on many types of investigations, and each section provides guidance on how to conduct those investigations, special reporting requirements, and where additional assistance can be obtained. Recall work, a special type of investigation, is covered in Chapter 7. Reporting an investigation is covered in Section 8.1.9 of this chapter.

8.1.2 - Investigations, Inspections, and Form 482? – When do you issue an FDA 482?

Investigations generally do not require an FDA 482, but there will be times when you need to issue an FDA 482, such as when you are at a manufacturing site or doing work like an *inspection* (e.g., collecting records at a manufacturer or shipper to document *interstate commerce*). Consult with your supervisor to determine the proper course of action for these situations. Investigations may be performed at a location not subject to FDA inspection.

8.1.3 - External Requests for Investigative Information – What if someone asks you about an investigation?

Investigations will naturally lead to interest from outside groups. Consumers, industry, press, and other external stakeholders may want information about your investigations. Do not reveal any information about an investigation to anyone outside of the agency without express permission. Direct any requests for information to the FDA's How to Make a FOIA Request webpage (https://www.fda.gov/regulatory-information/freedom-information/how-make-foia-request). Refer all media inquiries to the ORA Press Office at ORAPress@fda.hhs.gov (see IOM 1.7).

In the case of complaints where a sample has been collected from the complainant they may be informed of FDA's findings when an examination is made of the sample. When you collect a sample from a complainant, and they ask for analytical results, they may be told that the FDA will advise them of the general nature of the findings. Enter the complainant's contact information (name, address, phone number and email) into the Collection Remarks section of the Collection Report. Be sure to consult with your supervisor prior to collecting samples from a complainant. See IOM 4.4.3.3 and IOM 4.6.2.9. The Firm's Home District Compliance Branch will notify the Complainant of the Sample results.

8.1.4 - Office of Criminal Investigations – Who is OCI?

8.1.4.1 - OCI Responsibilities

ORA's Office of Criminal Investigations (OCI) has the primary responsibility for all criminal investigations conducted by the FDA, including suspected tampering incidents and suspected counterfeit products. Similarly, OCI has primary responsibility — and is the primary point of contact for — all law enforcement and intelligence matters.

8.1.4.2 - Reports of Criminal Activity

All reports of suspected or confirmed criminal activity, including suspected tampering or counterfeiting incidents, must be reported to the appropriate OCI field office or resident office without delay. Additionally, all threats or perceived threats against FDA-regulated products are to be referred immediately to the local OCI field office or to OCI headquarters. In those instances where OCI does not, or cannot initiate a criminal investigation in a timely manner, the division offices will consult with OCI to determine the proper follow-up.

8.1.4.3 - Liaison with Law Enforcement / Intelligence Community

OCI is the FDA's liaison with the law enforcement community for criminal investigations and related matters. In addition, OCI serves as the primary point of contact between the FDA and the intelligence community on all matters of mutual interest. OCI participates in numerous law enforcement and intelligence task forces both nationally and internationally including as a full-time representative at Interpol.

All contacts regarding requests or questions received from federal, state, or local law enforcement agencies or intelligence agencies are to be referred without delay to the local OCI field office. Similarly, law enforcement contacts to FDA headquarters or centers should be referred to OCI headquarters.

When FDA personnel receive information or requests from law enforcement or other agencies, they should obtain the caller's name, organization, and the details of the request. The caller should then be referred to the appropriate OCI component. After referring the caller to OCI, contact the affected OCI unit to provide the caller's information. This will prepare OCI of the expected contact. FDA personnel should not respond to inquiries concerning criminal investigations, including questions seeking confirmation of whether FDA is or is not conducting a criminal investigation.

8.1.5 - Types of Investigations – What situations lead to investigations?

You may conduct a variety of investigations in your career. Some types of investigations include, but are not limited to complaint investigations, disaster investigations, health fraud investigations, and product tampering investigations. When conducting any investigation, keep an open mind. Each investigation will be unique.

8.1.5.1 - Defective Products

A defective product is one that fails to do what it is expected to do. For example, a diabetes medication that fails to adequately control blood sugar levels that is prescribed for that reason. A defective product will typically result in a recall where the product may be destroyed or reconditioned.

Investigations into defective products could be initiated as a result of consumer or industry complaints that may indicate the need for follow up with the consumer or industry representative, which would be conducted as an investigation. Investigations are initiated in order to determine facts surrounding a claim related to the status or disposition of a subject FDA-regulated product. Subsequent findings would determine necessary follow-up and/or FDA action (e.g., inspection, sampling, product recall).

8.1.5.2 - Injury, Illness, Death

Escalation must occur when there is indication of a life-threatening injury/illness or adverse reaction or death. Follow up may vary depending on the situation. You may be asked to conduct investigations at complainants' residences or at firms to investigate any potential causes for the adverse reaction. Inspections at firms may also be warranted. These investigations could be assigned by Office of Emergency Operations (OEO), the Coordinated Outbreak Response and Evaluation (CORE) Network, or other agency components.

You may need to collect medical records or in some cases autopsy reports during these investigations. (See *Section 8.1.6.2* of this Chapter for guidance on obtaining medical records.)

When discussing complaints with a firm representative, do not provide any identifying information of the complainant, for example, name, phone number, or city or state of residence. Reports of adverse reactions may be received from consumers or health care professionals through voluntary reporting such as MedWatch. Reports may be received from state or federal partners.

NOTE: Follow any program specific guidance related to investigation preparation, collection of these records, etc.

8.1.5.3 - Criminal Investigations

During your work, you may encounter situations that involve criminal or fraudulent activity as defined under Title 18 USC and Title 21 USC. Criminal activity noted by FDA consumer safety officers (CSO) is typically cases of individuals and/or firms making false statements or providing false documents during the course of an inspection or other official activity. There are other violations of Title 18 and criminal violations of Title 21 USC that you may encounter.

Fraud is a separate criminal act from false statements and involves a false representation of a matter of fact whether by words or by conduct, including concealment of information, intended to deceive another for advantage.

In all cases of criminal activity including fraud, OCI is the primary investigative office for FDA. Gather as much initial information as possible and notify your supervisor. You may be asked to assist OCI in its investigation. If so, follow their directions and do not discuss the investigation with anyone outside of the investigation.

8.1.5.4 - Surveillance

During your inspectional, investigational, and other activities, be alert to anything which may be new or unusual or interesting from FDA's viewpoint such as:

- New firms.
- New products.
- New production and distribution practices.
- New equipment and industrial processes.
- Seasonal practices.
- Industry trends.
- Recent or on-going construction and plans for future expansion.
- Proposed products.
- New ideas the firm is contemplating.
- New products in the development stage.
- Activities about a firm's competitor.
- Plans for consolidation, mergers, diversification, etc.

If this information relates to a firm you are not currently inspecting, report the information using a Memo of Investigation and route through your supervisor appropriately. If the information relates to a firm being inspected report in the Establishment Inspection Report (EIR). (See *Section 8.1.9* for details on reporting your investigation.)

8.1.5.5 - Washouts

A “washout” is defined as an operation where you are unable to complete an assigned inspection. When you encounter a washout, you should determine the reason you are unable to conduct the inspection. For example, a firm that operates seasonally may be available for inspection later in the year. If a firm has moved, attempt to find the forwarding address of the firm. If the firm remains in the local area, do not treat it as a washout but conduct the inspection at the new location. Each washout should be investigated so that you are able to explain why you could not conduct the inspection. (See *Section 8.1.9* for details on reporting your investigation.)

8.1.5.6 - For Cause/Fact-Finding/Information Gathering

A for cause, fact-finding, or information gathering investigation is generally received by the division from an outside source like a center, ORA headquarters, or another division. It will generally be a request to obtain specific information from a firm or other source. One example could be obtaining interstate documentation from a shipper of a product to support a regulatory action, such as a seizure in another division.

8.1.5.7 - Complaints

A complaint is a notification that a product may be in violation of the laws and regulations administered by FDA . A complaint may be related to the following areas:

- Economic problems/misbranding (i.e., labeling).
  - Short weight.
  - Deceptive or misleading packaging and labeling.
  - Fraudulent products.
- Filth, decomposition, foreign objects, microbial or chemical contamination
  - Animal/plant/insect material.
  - Off appearance, off odor, or off taste.
  - Glass, metal, plastic, or other foreign objects.
  - Bacteria, yeasts, molds, or fungi.
  - Pesticides, industrial, or other chemicals.
- Defective products
  - Sub potency or super potency.
  - Particulate matter.
  - Failure to operate as intended.
- Adverse reactions
  - Allergic reactions.
  - Expected reactions.
  - Birth defects and problem pregnancies.
  - Death.
- Tampering

Complaints are received from various sources, including consumers, other government agencies, Congress on behalf of their constituents, trade associations, etc. *SOP-000544 – Consumer Complaint Procedure* describes the receipt and processing of consumer complaints in detail.
The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO), 1 (866) 300-4374 and Emergency.Operations@fda.hhs.gov, must be notified immediately of all death, life-threatening injury/illness, and suspected tampering complaints. OEM/OEO must also be notified of all complaints regarding infant formula/baby food. Advise OEM/OEO of the status of all such follow-up investigations.

As unique situations arise, OEM may provide guidance concerning the type of follow-up to be made.

Note: Link to SOP-000544 is available to FDA employees on the FDA intranet. The link is: http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=NE3SFDMGIZHCVHQIGE&static=false&mcuid=ANONYMOUS&mcsid=MOPVZCL2FFHJBIFCQG. Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.

8.1.5.7.1 - Types of Complaints

8.1.5.7.1.1 - Injury/Illness Complaints

A complaint indicating a life-threatening injury/illness, hospitalization, or death requires immediate reaction. It may require immediate investigation.

There are additional considerations with life-threatening and non-life-threatening injury/illness complaints. The prior medical history of the complainant may provide indications regarding allergies, drug side effects or drug-food/drug-drug interactions which may be responsible for the illness or injury. Medical verification should be sought in these situations.

8.1.5.7.1.2 - Non-Injury/Illness Complaints

Generally, these do not require immediate follow-up at the consumer level. Follow-up may include examining the parent lot, referral state, or local agency, or deferral until the next regularly scheduled inspection. Examples include mold in beverages, obvious filth, or insects in canned goods, etc. It may be possible that adequate investigation would be contacting the dealer, advising them of the nature of the complaint and requesting notification of any action taken. Non-injury/illness complaints do not need to be reported to the OEO unless product tampering is suspected, or the product is a baby food or infant formula.

8.1.5.7.2 - Sources of Complaints – Who provides us with complaints?

Complaints come from many sources. Regardless of the source, all complainants should receive a prompt and courteous response.

8.1.5.7.2.1 - Consumer

Consumers contacting field offices with complaints of injury, illness, or product defects should receive a prompt, courteous response, and assurance that their complaints will receive appropriate consideration. (See *SOP-000544 – Consumer Complaint Procedure*.)

8.1.5.7.2.2 - Industry

Industry complaints should be treated in the same manner as consumer complaints.

8.1.5.7.2.3 - Confidential Source

A Confidential Source is an individual who provides non-public information about an FDA-regulated entity/product, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity, and who requests anonymity.

Note: The term “Confidential Informant” is used only by OCI in relation to criminal investigations. ORA Complaint Coordinators and Investigators use the term “Confidential Source” during the course of their work. It is important to avoid the disclosure of a confidential source to a firm. The investigator conducting the investigation or inspection should not disclose the complainant’s information or report the information in the EIR. The complaint itself should be treated in the same manner as consumer complaints.

To maintain confidentiality, a memorandum regarding confidential information should be submitted as a separate operation, linked to the original report or submitted as an attachment to the EIR. There may be times when the report may be discussed in the EIR but, it will not disclose the source of the information. Discuss with your supervisor before including information obtained from a confidential source in the EIR.

8.1.5.7.2.4 - Whistleblower

A whistleblower is an individual who discloses information regarding an FDA-regulated entity/product that the individual acquired during their current or former employment, alleging potential violation(s) of federal law, or an illicit or unsafe product or activity. The complaint itself should be treated in the same manner as consumer complaints. It is important in these types of complaints that the identity of the whistleblower is not disclosed. The investigator should follow the same protocol as dictated in the Confidential Source section above by not disclosing the complainant's information or reporting the information obtained from the whistleblower in the EIR or any format where the complainants' information could possibly be released under the Freedom of Information Act.

8.1.5.7.2.5 – Anonymous Complainant

An Anonymous Complainant is an individual, usually a consumer or someone on behalf of consumer, who contacts FDA with concerns and provides information that a product in commercial distribution may be in violation of the laws and regulations administered by FDA and requests anonymity.

8.1.5.8 - Disaster/Emergency Response – How do we protect the consumer during a disaster or emergency?

The objective of FDA investigations in the aftermath of disasters is to determine whether or not foods, drugs including biologics, cosmetics, and devices affected by the catastrophe are safe for human and animal use; and if not, to effectively have them removed from commerce.
In disaster operations, FDA may assist state, local, and other federal agencies in removing contaminated or unfit merchandise from the market.

State and local officials usually assume direct responsibility for facilities and products under their jurisdiction, as their laws and regulations can be immediately invoked; however, FDA assistance is sometimes requested. Based on the size and scale of the disaster, FDA may receive an official request for assistance through FEMA, FDA/state Rapid Response Teams, or ad hoc through traditional state contacts.

If contacted by emergency response personnel for follow-up assignments, please work with your supervisor to engage district Emergency Response Coordinator (ERC) for further coordination.

8.1.5.8.1 - Preparedness

Disaster preparedness is the first step to ensure personal safety and response efficiency. Measures taken to prepare for and reduce the effects of disasters both personally and professionally are crucial before an incident occurs.

It is recommended as a preparedness measure that you familiarize yourself with your local Continuity of Operations Plan (COOP). COOP is the initiative that ensures that federal government departments and agencies can continue operation of their essential functions under a broad range of circumstances including all-hazard emergencies, natural, man-made, and technological threats, and national security emergencies. Today's threat environment makes COOP planning even more critical. Your local COOP will alert you to likely disasters for your geographic area.

Preparedness Resources:

FDA's Emergency Operations Plan (http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/EmergencyResponse/ucm381277.htm)

FEMA Preparedness (www.Ready.gov)

8.1.5.8.2 - Safety

ORA considers the safety of staff to be of the utmost importance.
In a disaster or pending disaster the personal protection of yourself and your family is your primary concern. Provide for your own safety as you perform your assigned FDA duties in a disaster area. Inoculations and protective clothing should be considered.
See Chapter S-Safety. Particularly S.8.1 - General Preventive and Protective Measures, https://fda.sharepoint.com/sites/insideFDA-EmployeeResources/SitePages/Occupational-Health-Services.aspx, S.17.2 -Immunizations, and S.9- PPE.

Disasters produce dangerous situations (e.g., high water, escaping gases, fallen electrical lines, damaged buildings, falling rubble, etc.), so care and extra safety precautions must be observed.

A Personal Safety Plan may be developed when dealing with disaster situations.

Be aware of hazards you may encounter while traveling in an affected zone such as power outages, damaged or impassable roads, and a lack of available supplies in the area.
Personal Protective Equipment (PPE) should be considered where appropriate. For example, appropriately fit-tested respirators such as N95 masks should be worn where there is a risk of inhaling pathogens. Each situation requires a careful evaluation and determination of effective PPE. Your supporting industrial hygienist should be consulted for guidance.

Safety Resources:

- DFI Field Alert #16 (http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigations/ucm010162.doc)

- ORA Safety Contacts (http://inside.fda.gov:9003/ORA/Offices/OORS/Safety/default.htm)
- ORA Radiation and Laser Safety Resources (http://inside.fda.gov:9003/ora/offices/oors/safety/ucm655438.htm)

8.1.5.8.3 - Response

CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.

8.1.5.8.3.1 - Use of Incident Command System (ICS)

During some disasters, FDA may implement an Incident Command System (ICS) for response. ICS is a standardized approach to managing incidents at the on-scene level. It is the combination of procedures, personnel, facilities, equipment, and communications operating within a common organizational structure. ICS is scalable and flexible and can be used for small, as well as large and complex, incidents and planned events.

As a CSO, you will typically be assigned under the Operations Section of the Incident Management Team (IMT). All operations you conduct, and your reporting structure will be provided by the IMT and shared via an Incident Action Plan (IAP). An IAP contains the incident objectives, the overall strategy for managing an incident, personal safety guidance, a comprehensive listing of the tactics, resources, and support needed to accomplish the objectives. (Note: Some CSOs with ICS position specific training may serve in a leadership role on the IMT.)

While serving on an IMT, your reporting will be to your team leader and not to your supervisor. The IMT will provide specific guidance for reporting. Your activities will be reported through the IMT and not through normal channels. Reporting may vary depending on the incident and its objectives. You will not be following reporting guidance later in this chapter.

8.1.5.8.3.2 - Management of Disasters without ICS

Specific investigation assignments should come from your supervisor and reporting will be through the normal means, unless directed otherwise.
Response Resources:

- Disaster Response Flow Diagram (DRFD) package (Exhibit 8-9)
- Incident Management Handbook (IMH) (http://inside.fda.gov:9003/downloads/policyprocedures/sopsbyprogram/emergencyresponse/ucm391230.pdf)

- Emergency Operations Plan (EOP) (http://inside.fda.gov:9003/downloads/PolicyProcedures/SOPsbyProgram/EmergencyResponse/UCM228297.pdf)
- Homeland Security Presidential Directive 5 (https://www.dhs.gov/publication/homeland-security-presidential-directive-5)

8.1.5.8.4 - Disaster Types

The types of natural and man-made disasters that affect FDA operations are:

8.1.5.8.4.1 - Floods

All flood water, regardless of its source, must be considered a polluting medium because of overflowing sewers, outhouses, decomposing livestock, street run-off water, etc.

Depending on the extent of the flood, first determine the locations of the major stocks of regulated products. Food and drugs will normally receive first priority. As stocks of goods are located, rapidly survey the extent of damage, then concentrate on affected materials. Use your camera extensively. Examine the walls of buildings, storage areas, and the top and sides of stacked or tiered goods for flood water residue, debris, and a well-defined high-water mark. Finished products, ingredients, and containers stacked above this line are still of concern because other problems probably exist (e.g., vermin defilement, failure of refrigeration, thawing of frozen items, etc.).

Any suspect material should be embargoed by local officials or held pending final disposition. Management is usually cooperative and willing to do things it may not normally do to get back to normal operations as quickly as possible. Cooperate with management but avoid hasty decisions.

Many products are quickly rendered unsuitable for human consumption by flood water. Items such as bread, cakes, cookies, candies, bulk flour, sugar, bulk liquids, and similar items not in jars or hermetically sealed containers can often be immediately hauled to disposable areas and destroyed.

Determine areas which have lost power. In facilities such as frozen food firms, and frozen or refrigerated warehouses, check the sites for length of down-power and condition of the products. If power is restored in time to avoid thawing, or prevent spoilage of refrigerated items, and products were not inundated, or otherwise affected, there is no need for further examination.

Even though flood waters may not have inundated the firm, the situation may have caused sewer and waste lines to backflush into basements and immediately drain out again. Debris or sewage particles along walls and on low floor surfaces or presence of sewage odors are evidence of backflushing.

Grain, cottonseed, soybeans, dried bean products, peanuts, and similar products may become flood damaged in terminal elevators, on farms, and in flat storage facilities. In

addition to flood water contamination, molding products may develop mycotoxin contamination. Examine susceptible products and facilities for damage, inundation, and mold.

Rodent activity may increase in flooded areas as the vermin seek food and shelter. Be alert to rodent defilement on products.

As lots of products are checked, embargoed, or released and the immediate situation returns to normal, firms will want to start operating. Prior to beginning operations, examine equipment and processing facilities for pollution and its aftermath. Plant operation must not be permitted unless proper cleanup and sanitizing is performed.

8.1.5.8.4.2 - Earthquakes

Extreme care must be exercised when working in earthquake areas. Do not enter severely damaged buildings.

Most damage from an earthquake comes from the aftershocks, falling debris, and resulting fires and flooding. Items under FDA jurisdiction are most likely to suffer physical damage, spoilage from lack of refrigeration, and/or fire and flood damage.

8.1.5.8.4.3 - Hurricanes and Tornadoes

Investigate following the guidance in *Flooding* Section above. In addition, examine products for evidence of physical damage caused by flying objects and crushing by debris. Physical damage to product containers may be extensive. Broken or leaking containers of materials such as chemicals, oils, fertilizers, etc., may have contaminated FDA-regulated products. See the *Chemical Spills, Hazardous Waste Sites, Wrecks* section below on chemical contamination from various sources.

8.1.5.8.4.4 - Chemical Spills, Hazardous Waste Sites, Wrecks

Chemical spills occurring on land or water can pose a serious threat to the environment and contaminate FDA-regulated products both directly and indirectly. See IOM 3.2.11 for information.

In wrecks, the physical impact usually causes most damage. Toxic items in the same load may rupture and add to the contamination. In train wrecks, other railcars loaded with chemicals, oils, or other contaminating materials may rupture and contaminate food and drug products in otherwise undamaged cars. Removal of the wreckage may cause further physical damage or chemical contamination. Exposure to weather may also adversely affect the products.

Do not overlook the possibility that runoff of toxic chemicals from wrecked and ruptured cars may contaminate adjacent or nearby streams supplying water to downstream firms under FDA jurisdiction.

Hazardous waste sites also pose a hazard to the immediate environment and other locations off-site, if runoff contaminates nearby surface waters or, if leachate, contaminates ground water supplies.

8.1.5.8.4.5 - Fires, Explosions, Riots

FDA operations following these disasters are usually localized and do not normally involve many personnel or extended resources.

Examine products for exposure to excessive heat, physical damage from flying objects, falling debris, and lack of refrigeration in down-power areas. Examine for water damage from firefighting activities and handle these as a flooding situation. Be alert for possible pollution from using non-potable water in firefighting.

Firefighting often involves use of chemicals. Examine products for residues from possible toxic fire extinguishing materials and question fire authorities regarding this issue.

In addition, chemical contamination in fire disasters can also be present from other sources, including:

1. Stored chemicals rupturing from heat or from impact of falling debris.
2. Spraying or leaking chemicals (liquid, powder, dust, granules) as damaged containers are being removed or salvaged from the fire area.
3. Tracking of chemical material from contaminated areas to other areas by fire crews or others.
4. Burning or melting plastic containers, insulation, and other building materials.
5. Leaking fuels, storage batteries, anti-freeze, etc., from burning, damaged or overheated equipment.
6. Chemicals from melting or vaporizing electrical insulation and, in particular, cooling chemicals from leaking or exploding electrical transformers. Large commercial transformers are often directly involved in the fire area and may leak or explode from the heat, spreading toxic liquid chemicals (some transformer oils contain con-centrations of PCB) over a large area, even contaminating products in non-fire areas.

8.1.5.8.5 - Bioterrorism

The field was issued guidance from 2001 which includes the following:
If a bioterrorism act is suspected, FDA staff should not collect or accept samples from any local, state, or law enforcement agency as such actions will be coordinated by OCI and the FBI, as appropriate. If an FDA-regulated product is suspected in a tampering, please call OEM/OEO immediately. In the FBI/OCI determines the product is not suspect, OEM/OEO will issue further guidance to the division office.

Office of Emergency Operations / Office of Emergency Management (OEM/OEO) emergency operations 24-hour phone number is 1 (866) 300-4374. The e-mail is emergency.operations@fda.hhs.gov.

For additional information see Guidance to the Field on Bioterrorism (10/17/2001) (http://inside.fda.gov:9003/downloads/policyprocedures/guidanceregulations/fieldinvestigations/ucm023333.doc). *(Note: This link is only available on the FDA Intranet site and cannot be accessed by individuals outside the FDA network. Requests can be made through the FOI process described in Section 8.1.3)*

8.1.5.8.6 - Embargoes

See IOM 3.3.1 and IOM 2.7.1.

FDA does not have embargo authority, but does have administrative detention authority as specified in:

- The Federal Meat Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/federal-meat-inspection-act)
- The Poultry Products Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/poultry-products-inspection-act)
- The Egg Products Inspection Act (https://www.fsis.usda.gov/policy/food-safety-acts/egg-products-inspection-act
- Certain parts of the FD&C Act, namely Section 304(g) [21 U.S.C. 334(g)](g) [21 U.S.C. 334(g)] for medical devices, drugs, and tobacco and Section 304(h) [21 U.S.C. 334(h)] for human and animal food

States and local jurisdictions have embargo authority over FDA-regulated products. Embargoes are an effective tool for keeping adulterated and misbranded products from the consumer market. State and local embargoes can be employed immediately requiring the merchandise be held, destroyed, or reconditioned without time consuming delays. Some state and local embargo powers are limited to the length of time the product can be embargoed and a minimal quantity or value. In these cases, the use of federal administrative detention, injunction, and seizure action should still be considered. Your division will determine if embargoes are warranted and work with state or local authorities to obtain them.

8.1.5.8.7 - Field Operations

On-site inspectional and investigational activities will normally be conducted with other FDA personnel and state or local counterparts.

An assessment must first be made of the disaster area to determine the extent of damage, and the amounts and kinds of merchandise involved. This may be done by contacting local Emergency Operation Centers on current conditions, and from firm and mapping details of the impacted area provided by the OEO Geographic Information System (GIS). If an IMT is activated the Planning Section and Safety Officer will perform this assessment.

Whether operating within an IMT or not, once personnel are mobilized and assignments are issued, operational procedures will be similar, regardless of the type of disaster. Normally, you will search, identify, and investigate foods, drugs, devices, and cosmetics for actual or possible contamination and taking the necessary steps to preclude their use until they are released, reconditioned, or destroyed.

CAUTION: Although procedures in this subchapter do not cover disasters resulting from a radiological event (presence or release of radioactive materials), it is possible you may discover products suspected of contamination by radioactive materials in the disaster area. If you suspect the presence of radioactive materials, take no action on the materials yourself, but have the area cordoned off at once. Notify the command official (official in charge) and immediately contact your IMT or supervisor, as applicable, to alert the radiological health representative and the state radiation control agency. Follow their instructions.

When in doubt as to the condition of any materials affected, request holds or embargoes pending final outcome of further examinations. See *Section 8.1.5.8.6.*

8.1.5.8.8 - Field Examination and Samples

Field examinations are an effective tool for determining adulteration or misbranding during disaster investigations. Judge the extent of field examination and sample collections necessary, based on the nature and magnitude of the disaster.

In major catastrophes, large numbers of samples may not be necessary because of obvious visible contamination and the emergency disposition powers invoked by state and local officials. In minor local disasters, such as fires, riots, train wrecks, truck accidents, or shipwrecks, lots may be held pending outcome of examinations and extensive sampling may be required.

Field examinations should focus on obvious adulteration, such as physical damage to products or containers, or damage to labeling.

Examine bulk containers and their contents, including underground storage tanks. Examine material in rail cars, truck trailers, and storage silos. Be especially alert for rail car and trailer movement. These may quickly disappear, as clean-up crews arrive.

8.1.5.8.9 - Product Disposition

Lots under embargo, or voluntarily held pending examination or analysis, must be secured until the examination or analysis is completed, and a release decision is made. If the material can be released, it is returned to the owner.

Depending on the circumstances and the magnitude of the disaster, segregation, destruction, or reconditioning of affected goods may be accomplished in the immediate area or the materials may be moved to distant locations for further manipulation.
FDA normally opposes movement of affected goods since control of the lots is difficult. However, in cases of widespread disasters, reconditioning centers established in non-disaster areas may be the most efficient way to handle the problem.

8.1.5.8.9.1 - Segregation

The segregation process often creates a multitude of problems, especially when insurance claims agents and salvage firms become involved. You are not to segregate materials yourself. This is the responsibility of the owner or his agent. You should advise them what constitutes releasable conditions. After segregation, you may be instructed to advise them about product release based on your examination and/or laboratory results.

8.1.5.8.9.2 - Destruction

It is not your responsibility to say how condemned products are to be destroyed. This is a concern of the owner and the state or local health agencies that condemned the products. FDA may be asked to aid in or recommend destruction methods. The most common destruction method is crushing and dumping in a land fill in approved areas. See IOM 2.6.1. Destruction methods usually are worked out with state or local officials. The final decision in major operations may be required of the command officials or higher headquarters, especially if the environmental impact is significant.
Control products to be destroyed and protect them from pilfering at destruction sites.

8.1.5.8.9.3 - Reconditioning

Affected products may often be reconditioned depending on the condition of the product, its container, type of product, intended use, and extent and type of contamination.

Any reconditioning must be closely supervised, with proper safeguards for product accountability. Control must be maintained over the complete operation, with proper disposition of the rejected portion and the reconditioning of the acceptable portion performed to the satisfaction of all health officials.

Certain food products which cannot be salvaged for human or animal use might be of use in non-food or non-feed industries. However, these must be denatured to render them unfit for food or feed use. Firms must account for the amounts of product denatured, to whom it was sold, and the final use of the product. Examination of the product at its final destination and/or a spot check may be required to assure it is utilized in non-food or non-feed products. Reconditioning plans should be reviewed by the division's Compliance Branch in consultation with the appropriate center or by the IMT if ICS is being used for the incident.

It is your responsibility to assure the firm is following the reconditioning plan and that no product is diverted from the plan.

8.1.5.8.9.4 - Relabeling

Relabeling may be the only reconditioning required if damage is solely to the label and all the following conditions are met:

- The new label contains all mandatory information, is not misleading in any way, and conforms with the FD&C Act in all other aspects.
- Label codes are carried over to the new label.
- The product is not contaminated; and

- The container has its original integrity.

8.1.5.9 - Counterfeiting and Tampering

8.1.5.9.1 - Reporting Contacts

All reports of counterfeiting, tampering, or tampering threats must be immediately reported to the Office of Criminal Investigations (OCI) headquarters office, Special Agent in Charge-Headquarters Operations (SAIC-HQS OPS) at 240-276-9500 and the Office of Emergency Management (OEM)/Office of Emergency Operations (OEO) at 1 (866) 300-4374 (24 hours); or through CMS following SOP-000544.

If the complaint or report involves a United States Department of Agriculture (USDA) regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's *Report Suspect Criminal Activity* website: (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm). OEM/OEO can be notified by e-mail at emergency.operations@fda.hhs.gov and by phone 24 hours a day at 1 (866) 300-4374.

Do not conduct any investigation into these reports unless you have been directed to do so by management following their meeting with OCI.

8.1.5.9.2 - OEM / OEO Responsibility

OEO/OEM is the focal point for communications; especially in those counterfeiting/tampering cases where regional/national coverage is necessary. Alert OEM immediately to all suspected or confirmed counterfeiting/tampering incidents, whether or not there is an injury/illness involved, especially if media attention will be initiated by any source.

8.1.5.9.3 - Coordination with Other Government Agencies

The Federal Bureau of Investigations (FBI) and the USDA share enforcement of the Federal Anti-Tampering Act (FATA) with FDA as described below:

1. FBI Responsibility - The FBI has concurrent jurisdiction under the FATA over products regulated by FDA. The FDA understands the FBI's primary interest in the FATA matters will be to investigate; particularly, those cases which involve a serious threat to human life or a death. SAIC-HQS OPS or the local OCI field office will coordinate all referrals to the FBI in accordance with agency policy.
2. USDA Responsibility - The USDA will investigate and interact with the FBI on counterfeiting/tampering of products regulated by USDA. If a counterfeiting/tampering complaint or report is made to an FDA district office and involves a USDA-regulated product, the district office should report it directly to the USDA and notify OCI, SAIC-HQS OPS, and OEM/OEO immediately. Notification of OCI may be done online at OCI's *Report Suspect Criminal Activity* website: (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

Isolated incidents of counterfeiting/tampering not investigated by OCI and not meeting the criteria for FBI or USDA follow-up, may be referred to the appropriate state or local

investigative agencies, as outlined in section 8.1.5.9.4. The appropriate center should be consulted in these cases. Assistance should be provided to cooperating officials as necessary or where requested.

8.1.5.9.4 - Authority & Responsibility

FDA is authorized to investigate reported counterfeiting/tampering of FDA-regulated consumer products under the FATA, Title 18, USC, Section 1365 and Title 18, USC, Section 2320. See IOM Exhibit 8-1. In most cases, the authority for such investigations is also found in the FD&C Act.

OCI has the primary responsibility for all criminal investigations of counterfeiting/tampering/threat incidents of FDA regulated products. Given that responsibility, OCI field offices will coordinate responses to counterfeiting/tampering reports with the district offices they deem appropriate, to ensure initial investigative steps are taken in a timely and efficient manner.

In those incidents where OCI does not, or cannot, initiate a criminal investigation, they will inform the division of their decision and the division will determine the proper follow-up, which could include further investigation by the division or referral to local or state authorities. The division will keep OCI informed of their follow-up activities and any relevant changes in its status. Prior to initiation of any tampering investigation, you and your supervisor should evaluate the situation from a personal safety perspective. You and your division management may also need to determine if a situational plan is warranted. Refer to IOM 5.2 - Personal Safety, and IOM 5.3.1.1 Situational Plan, for more information.

8.1.5.9.5 - Release of Information

During any investigation related to counterfeiting or tampering, no information should be released without management approval. If there are inquiries about the investigation, contact your supervisor.

8.1.5.9.6 - Investigation

The purpose of these investigations is to determine if counterfeiting/tampering has occurred; the seriousness of the problem; the quantity of affected products on the market; the source of the counterfeiting/tampering; and quick removal from consumers or commerce of any contaminated product. OCI will seek to identify and initiate criminal prosecution of those persons responsible for criminal activity associated with counterfeiting/tampering/threat incidents.

FDA will investigate reports of counterfeiting/tampering associated with FDA-regulated products. Priority will be given to reports of death, illness, injury, or a potential health hazard. Adhere to existing procedures and instructions as outlined in the IOM and RPM when conducting counterfeiting/tampering investigations, inspections, sample collections, special investigations, and related activities including interviews, record examination, direct observation, affidavits, etc.

8.1.5.9.7 - General Procedures

Counterfeiting/Tampering incidents historically have occurred in unpredictable forms and products. Standard operating procedures (SOPS), in most cases, will suffice for these investigations. As events take place, specific instructions for some investigations may be provided by OCI headquarters and/or your division office. Expeditious resolution is important, especially when a health hazard may be involved.

Attempt to answer the following questions as rapidly as possible:

- Has counterfeiting/tampering occurred, or can the condition of the product be explained by other means?
- Is death, injury, or illness associated with the report and, if so, does it appear to be caused by the product counterfeiting/tampering?
- Does the incident appear to be isolated or wide-spread?
- Is it likely other, similarly affected FDA-regulated products remain in distribution, and if so, what is the extent and magnitude of distribution?
- If the incident involves more than a single container, could counterfeiting/tampering have occurred at the production facility or in the distribution chain rather than at retail?
- Can specific persons or points in the distribution chain be identified as possibly causing the problem?

Be sure to coordinate your efforts with OCI SAIC/IOD HQS OPS and OEM/OEO.
In many counterfeiting cases, ORA investigators and OCI agents conduct joint inspections/investigations at the distributors. It is the purpose of the ORA investigators to document receipt and distribution of counterfeit products and to discuss voluntary recall of those products. OCI agents will at the same time conduct their investigation into the knowledge and source of the counterfeit products. It is not your purpose to accompany the OCI agent during his/her investigation.

8.1.5.9.8 - Sampling

8.1.5.9.8.1 - Tampering Cases

Whenever a sample is collected for suspected tampering, you must collect an authentic sample of the same product. It should be from the same lot and code, if at all possible. The sample size for the authentic portion is at least six in-tact units. Follow normal sampling techniques; however, recognize that there may be forensic evidence available such as fingerprints and hair that can be lost if the sample is not handled properly.

The Forensic Chemistry Center should be contacted prior to sampling. They can give specific directions regarding sampling in each situation, especially related to the preservation of forensic evidence like fingerprints.

Samples should be packed to avoid movement of the product container within the bag. Individual dosage units from previously opened containers can be protected by removing them from their container utilizing spoons or forceps. Secure them in separate containers so they do not rub or smear possible evidence. Further guidance can be found in the FBI "HANDBOOK OF FORENSIC SERVICES" (https://www.fbi.gov/file-repository/handbook-of-forensic-services-pdf.pdf/view). As a precaution, rubber gloves may be worn inside of cotton gloves as protection against toxic or caustic substances.

Ship samples with extreme care to ensure their integrity. Thoroughly describe your sample and its characteristics on the collection report (C/R) to facilitate analysis. Include any descriptive terms used by individuals associated with the complaint. If special instructions to preserve fingerprints or for further handling are indicated, they should be noted on the C/R. If speed is imperative, consider hand delivery to the lab.

8.1.5.9.8.2 - Counterfeiting Cases

If sampling is indicated during an investigation of counterfeiting, follow the directions from OCI or the Forensic Chemistry Center regarding collection, packaging, and shipment of the sample. Authentic samples should only be collected when requested by OCI in consultation with FCC.

8.1.5.9.9 - Complainants

Some complaints about “foreign objects” may be tampering complaints. The complainant may state they found something in a product. You should be aware that any complaint investigation of foreign objects may become a tampering investigation.

Consumers are likely unaware of the provisions of the Federal Anti-Tampering Act (FATA). A general discussion of the FATA, its provisions for investigation, filing of false reports, and counterfeiting/tampering can be useful and informative to those individuals. Consumers are often unaware that merely filing a false report is a serious crime and once aware may rescind previous statements. In general, this would close an investigation, but you should discuss this with your supervisor.

Prior to concluding your interview of the complainant, obtain a signed affidavit attesting to the circumstances of the complaint, as directed by IOM 4.4.5. Include a statement in the affidavit similar to the following, "I have been informed of the provisions of the Federal Anti-Tampering Act and also that the providing of false information to the federal government is illegal." It is permissible to pre-type this statement at the bottom of an affidavit, FDA 463a, and photocopy it before use if you have a large number of counterfeiting/tampering complaints to investigate.

8.1.5.9.10 - Continuance of Investigation

Some investigations may continue after the interview and sample collection from the consumer. If you are directed to continue the investigation at the retail, distribution, or manufacturing

sites, obtain specific guidance from your management or OCI before proceeding. You may be conducting an inspection at a firm simultaneously with an OCI investigation. You should not disclose to the firm officials anything about an OCI investigation.

8.1.5.9.11 - Refusals

All refusals encountered during counterfeiting/tampering investigations should be documented using existing procedures. Refusals of requests should be documented in detail. Assure the firm is aware of the non-routine nature of the request. If a search warrant or other court order is necessary, OCI will lead or direct this part of the investigation. Report all refusals to the local OCI field office.

8.1.6 - General Investigative Techniques – What do I do during an investigation?

8.1.6.1 - Interviews

An interview is a one-on-one structured conversation to obtain accurate, reliable information. To gain the most facts and information, be prepared and conduct the interview methodically with a set purpose.

8.1.6.1.1 - Preparation

Interviews may be conducted in various agreed upon meeting places. Choose a non-threating place for the interview, such as a conference room or private office free from distractions or interruptions. Silence your phone to avoid incoming calls. If possible, conduct the interview away from the person's normal area of business. If interviewing a consumer at their home, try to interview them in an area of their home that has the least distractions. If possible, conduct the interview sitting directly across from the interviewee.

Begin by researching your topic. Set a specific purpose and objectives for what you want to learn during the interview.

8.1.6.1.2 - The Interview

- Set the tone. In most cases, you may tell the interviewee what they can expect. Start out with generic or easy-to-answer questions to establish a baseline and to put the subject at ease.
- Avoid asking leading questions. Ask open-ended questions that encourage the interviewee to talk and provide a full answer rather than a "yes" or "no" (e.g., Tell me about…, How did you…, Why was this…, etc.) Avoid combining more than one idea into the same question. Frame the question to generate an answer one fact at a time. Avoid questions that are accusatory or that trigger a defensive response. 'Yes' and 'no' questions may be used at the end of the interview to affirm facts.
- Keep an open mind.
- Do not express your opinions, thoughts, and your own conclusions about the situation or what the interviewee says. You are trying to learn information and facts from the interviewee so avoid being too familiar with the topic in your responses. Set aside any potential biases while conducting the interview.

- Take detailed notes or have another CSO present to take notes. This is extremely helpful since you are focused on the objectivity of the interview. If taking notes makes the interviewee uncomfortable or hinders the interview, you may take notes immediately after the interview and identify the time between the interview and your notetaking and explain the circumstances for not taking contemporaneous notes during the interview. Only use quotes ("…") if you are certain they are exact. It is a good practice to read a quote back to the interviewee to confirm its accuracy.
- Pay attention to the subject's verbal and non-verbal communication.
- Ask for clarification and more detail if responses are not clear to you during the interview. Repeat answers back to the subject to ensure you heard the information correctly. Ask if documents exist and to support any part of the interviewee's story. Collect any available relevant documents.
- Follow-up questions may help establish additional facts. If your questions are avoided or the answers seem evasive, try rephrasing the question and ask it again. You may also change topics and return to an issue later.
- Allow the interviewee enough time to answer your questions and avoid interrupting them. Sometimes silence can be a tool to prompt further explanation or reaction. Before concluding the interview, ask the subject if there is anything else they would like to provide or discuss. Ensure that the interviewee has your contact information in case they recall any more material information later.
- Interviews and discussions with complainants where tampering is suspected or alleged, should include a discussion of the Federal Anti-Tampering Act (Exhibit 8-14). This discussion needs to be documented in the investigation report/memo. See IOM 4.4.3.3

8.1.6.1.3 - Safety

Developing a Situational Safety Plan may also be required. Refer to IOM 5.2
In preparation for any consumer complaint interviews, you should take your personal safety into consideration. Refer to IOM 5.3.1.1 for more information.

8.1.6.1.4 - Basic Information to Obtain

Obtain an accurate and complete description of the product, e.g., brand name, product name, flavor, or variety, how packaged, storage conditions required (i.e., refrigerated or shelf stable) etc. Refer to *Consumer Complaint Procedure (SOP-000544)* Section 6.1.4.

It is important to accurately determine the sequence of events leading up to the complaint.

You cannot rely on consumers responding to follow-up calls or providing additional information later.

8.1.6.2 - Medical Records

In investigating complaints where the complainant was seen by a health professional, contact the health professional concerning the nature of the alleged illness/injury, and the relationship to the product. You may occasionally find the complainant has not mentioned the product to the health professional as a potential cause of the illness or injury. Use judgment as to the usefulness of

collecting medical records. Examples of medical records to collect include: Admission History and Physical; Emergency Room/Clinic Record of the event if patient not admitted; Discharge Summary; Autopsy Report; and Death Certificate. See also IOM 5.6.11.4.

If collection of medical records is necessary, use the letter template found in Exhibit 8-2. It may be necessary to use multiple letters if medical records are at different locations. If you encounter resistance from the medical professionals in providing records, you may refer them to 45 CFR 164.512(b) which explains the exemptions allowing FDA access to the medical records.

FDA is exempt from the HIPAA Privacy Rule as a public health authority. If a situation arises in which information sharing is impeded by the belief that FDA lacks authority to receive this information, you may share the language below during disease outbreak investigations or consumer complaint follow-up. References are provided for further information.

"The Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to 'a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including…the conduct of…public health investigations'[1]. Per the Privacy Rule, 'public health authority means an agency or authority of the United States…including the employees or agents of such public agency…that is responsible for public health matters as part of its official mandate'[2]. FDA, as a public health authority responsible for ensuring the public health and safety with regards to FDA-regulated products, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal Food, Drug and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.

"The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to the FDA for certain public health activities and purposes, provided that the disclosure is limited to the minimum amount necessary. During FDA follow-up to reports of illnesses potentially associated with FDA-regulated products, access to personal privacy information including names and contact information is necessary in order to ensure timely follow-up and, potentially, removal of implicated products from commerce. FDA is also responsible for safeguarding personal privacy information released to us according to the Freedom of Information Act and the Privacy Act[3] and our information disclosure regulations[4], and is obligated to comply with

[1] 45 CFR 164.512, from the Privacy Rule, available at https://www.law.cornell.edu/cfr/text/45/164.512

[2] 45 CFR 164.501, also from the Privacy Rule, available at https://www.law.cornell.edu/cfr/text/45/164.501

[3] 5 USC 552, 5 USC 552a, from The Privacy Act of 1974 5 USC 552a (as amended), available at https://www.law.cornell.edu/uscode/text/5/552 and https://www.law.cornell.edu/uscode/text/5/552a

[4] 21 CFR Parts 20 and 21, from FDA information disclosure regulations 21 CFR Parts 20 and 21, available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=20

all applicable protections, procedures, and legal requirements against the unauthorized disclosure of this information.

"Consequently, personal privacy information including case names and contact information should be shared by state and local health departments with FDA authorities during an investigation of potentially adulterated FDA-regulated products, including illness outbreaks potentially associated with FDA-regulated foods. Prompt information sharing speeds the agency's investigation and can prevent additional illnesses and/or deaths due to an adulterated FDA-regulated product."

If the investigation is related to an outbreak/illness and the Office of Emergency Operations or Coordinated Outbreak Response and Evaluation is coordinating the incident and a medical officer has been assigned to the investigation it is preferred that the CSO, with supervisory concurrence communicates with the medical officer about the documents to collect prior to the collection. In the absence of a medical officer being assigned or available, the CSO in collaboration with the supervisor, should collect medical records most relevant to the incident. Once collected, the Office of Emergency Operations or CORE if involved, or the supervisor in consultation with their management should identify a medical officer to review the records.

The records containing personal identifiable information (PII) and medical information need to be protected. All medical information sent to the medical officer electronically needs to be encrypted. Hardcopy records shipped to the medical officer need to include shipment tracking information and request signature upon receipt. The medical records should be addressed to the attention of the specific medical officer who will be conducting the review.

Any hard copy medical records in the possession of the CSO after sending to the medical officer or returned by the medical officer, should be placed in a sealed envelope, identified to contain PII and medical information and filed with the investigation memo.

When collecting medical records from a Department of Defense (DoD) medical facility, identify yourself to the commanding officer of the facility or representative and request authorization to examine and copy records. Please note that DoD Directive 6040.2, Release of Information from Medical Records authorizing release of medical information to government agencies, has been rescinded by DoD; if the representative of the facility requests a letter authorizing release, use the same letter as above.

If the hospital does not accept the FDA letter for Authorization for Medical Records Disclosure, obtain and complete the one the facility provides.

Collect all medical records pertinent to the investigation. See IOM 5.6.5.

References are available at: https://www.law.cornell.edu/cfr/text/45/164.512 and https://www.cdc.gov/mmwr/preview/mmwrhtml/m2e411a3.htm.

8.1.6.3 - Sample Collection

Chapter 4 covers general sample collection methods and authority. In general, collection of samples during an investigation will be directed by the assignment or in discussion with your supervisor. Opened containers of product are rarely sampled.

Prior to initiating sample collection, you may consider contacting the home division of the manufacturing plant. They may be aware of an existing issue related to the product and problem. Samples should be collected immediately, while they are available.

When a consumer portion is collected, intact containers of products of the same lot should be collected from the retail and wholesale levels if available. When collecting samples at retail or wholesale, ask if the firm is aware of any other complaints concerning the product. Refer to IOM 4.3.4.1 for additional information concerning collection of consumer portions. Maintain the confidentiality of the complainant. If the distributor inquires about holding or recalling the product, refer them to your supervisor.

8.1.6.4 - Internet Investigations

The internet can provide useful information when conducting many types of investigations, including obtaining basic background information. Often you can use your government issued computer or cell phone for basic firm information (e.g., hours of operation, key personnel, location, directions, etc.). In these cases, you are using the internet as a tool to assist as you determine where and how to collect information and conduct your investigation.

When conducting specific internet investigations and documenting evidence online, refer to Introduction to Internet Investigations

(https://fda.sharepoint.com/sites/insideFDA-ORA-Office-of-Partnerships-and-Operational-Policy/SitePages/Health-Fraud-Branch.aspx)

Note: This website is on the FDA Intranet and not accessible outside of the FDA Network.

8.1.7 - Locations for Investigations – Where could you conduct an investigation?

Some examples of locations for investigations include:

- Retail establishments.
- A consumer's residence.
- Other government agencies.
- Location agreed upon with a complainant.
- Hospitals/physicians' offices.
- Online.

Depending on the circumstances involved, an investigation can be performed at almost any location.

8.1.8 - Internal and External Organizations Involved - Who else will I encounter during an investigation? Why are they involved?

The agency works cooperatively with many outside organizations, primarily other federal government agencies and state, local, tribal, and territorial (SLTT) authorities. Internally, you may work with individuals from ORA headquarters, OCI, other programmatic divisions or center employees. Some of these organizations become involved due to contractual obligation, statutory obligation, request for expertise, or memorandum of understanding (MOU). Chapter 3 of the IOM provides information about major organizations that FDA interacts with, both federal and state.

8.1.8.1 - Interagency Referral

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting plant inspections. If you find information during the course of an investigation that may be relevant to another federal agency, a referral request can be made by filling out an online form https:/www.accessdata.fda.gov/scripts/IRF/.

Primary regulatory authority may belong to FDA or another agency. It is important to be aware of which organization has primary regulatory authority during an investigation.

For Grade A Milk products, raw molluscan shellfish, and retail food operations, within ORA, the Office of State Cooperative Programs (OSCP) has lead responsibility. For these cooperative programs, the state has primary authority for investigations. FDA often accompanies and assists states during investigations through the Office of State Cooperative Programs. If your investigation involves Grade A Milk or Milk Products, raw molluscan shellfish, or retail food operations, contact the Office of State Cooperative Programs before investigating.

8.1.8.2 - Intra-agency/Cross-Program

Outside of ORA, you may be involved other components of FDA. FDA staff work closely with one another to ensure the safety, efficacy, and security of FDA-regulated products. FDA functions are organized into the following:

- The Office of Foods and Veterinary Medicine (OFVM) provides oversight of FDA's food and feed programs as well as leads the implementation of the FDA Food Safety Modernization Act of 2011 (FSMA). OFVM includes the Center for Veterinary Medicine (CVM) and the Center for Food Safety and Applied Nutrition (CFSAN) which includes the Coordinated Outbreak Response and Evaluation (CORE) Network.
- The Office of Medical Products and Tobacco (OMPT) provides high-level coordination and leadership across the centers for drugs, biologics, medical devices, and tobacco products. This office also oversees special medical programs.
- The Office of Global Operations (OGO) is focused on globalization and import safety of food and drug production and supply. OGO provides direction and support to ORA and the Office of International Programs (OIP).

8.1.9 - General Investigation Reporting - How do I report my investigation? How do I get credit for the time I spent on it?

Reporting an investigation is almost always done using a memorandum (see Exhibit 8-3) and captured as an operation in eNSpect (explained in more detail below). The format of the investigation memo is not as defined in sections as an establishment inspection report (EIR). As a general guideline you can first summarize why or give the reason for the investigation, what was covered, and briefly state the findings. After this, you can go into detail about how you conducted the investigation and what you found. Reporting the course of your investigation and your findings chronologically works in most situations. For long narratives, using headings will make it easier for the reader to follow your reporting. Some types of investigations have forms that need to be completed in addition to the narrative within the memo. For example, FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations.

For import specific investigations see IOM 6.6.3.

8.1.9.1 - Entering investigation operations in eNSpect

eNSpect is used to capture information about the assignment, the establishment, and the investigation. Investigation operations are reported in eNSpect as either a Domestic Investigation (OP13) or Foreign Investigation (OP15). General information on how to complete these operations in eNSpect field client are provided below. (For complete instructions, refer to the eNSpect Resources Site for the current eNSpect User Guide and eNSpect training.) The "Investigation" tab in eNSpect includes the "Details," "Time & Coverage," and "Endorsement" pages.

The "Endorsement" page has three sections: Endorsement, Attachments, and Supervisor Feedback. Attachments, such as the investigation memo, are uploaded to support your findings under the "Attachments" section of the endorsement page. All three sub-sections must be completed, and each has a maximum of 4000 characters per text box. The narrative entered in these sub-sections will depend on several factors (e.g., program/division, type of investigation, assignment). If the character limit prevents you from describing all relevant facts, an investigation memo should be prepared and uploaded under the "Attachments" section. If the space is adequate to report your investigation, you may not need to prepare a memo. For example, reporting OEI improvement activities and firms determined to be out of business (OOB) are two situations where a memo usually is not necessary. However, this can also depend on your program and/or division procedures. Programs of divisions may require a memo for all investigations. Consult with your supervisor if you are unsure whether a memo is required for the investigation.

Your supervisor or other designated individual will review and endorse the investigation report (OP13 or OP15) in eNSpect. An inspection (OP11 and OP12) can be converted to an investigation (OP15 and OP13, respectively) in eNSpect when you were unable to complete the inspection (often referred to as a "washout"). Obtain supervisory concurrence before converting an inspection to an investigation due to a washout. For example, your supervisor may want you to hold onto an inspection assignment and inspect a seasonal firm later in the year rather than converting the inspection to an investigation as a washout.

Reasons to convert an inspection to a washout include the following: Out of Business (OOB); Not Official Establishment Inventory (NOE); Inactive (INA); Seasonal (SEA); Operational but not an FDA obligation (OPR); Pre-Production (PRE-PROD), and Firm does not meet assignment criteria (OPR). The information reported in your investigation, especially the reason for the investigation, may be helpful to future investigators. If the investigation finds further action is recommended, do not convert the associated inspection assignment to a "washout" in eNSpect. Report the operation using an ad-hoc eNSpect investigation (OP13 or OP15). Do not return the associated inspection operation (OP12 or OP11) to FACTS for conversion to an investigation. An example of a further action would be a request for Import Alert because of an inspection refusal in a foreign country.

8.1.9.2 - Investigation memo: format, content, endorsement, and routing

Exhibit 8-3 demonstrates the general format of a memorandum of investigation (investigation memo), which includes the originating division/office; responsible firm; FDA Establishment Inventory (FEI); to/from; date; and subject. When writing an investigation memo, consider the following:

- Document all pertinent information (e.g., who, what, when, where, why). At a minimum, the investigation memo should contain the following information: the reason for the investigation; background and history, if any; findings; and recommendations.
- Provide details of how you conducted the investigation and describe pertinent data, references, attachments, etc.
- Headings may be used if it contributes to presenting your report in a clear, logical, and concise manner.
- Routing for the memorandum should be included. Consult with your supervisor if unsure of the correct routing information to include.

8.1.9.3 - Reporting complaints/follow-ups

Refer to *SOP-000544, Consumer Complaint Procedure*, in the Quality Management Information System (QMiS) for detailed instructions on intake, tirage, escalation, dispositioning, and follow-up of consumer complaints of FDA-regulated products received by and/or submitted to ORA personnel.

If you conduct an inspection to follow-up on a complaint, any findings related to the complaint should be documented in the Establishment Inspection Report or in one of the following ways for an OP13/OP15, if not involving confidential sources, whistleblowers, etc.,
If you conduct an inspection as above, but it involves a confidential source or whistleblower, follow directions for reporting provided in Consumer Complaint section related to Confidential Sources or Whistleblower.

Information contained in the investigation memo or sub-sections of the "Endorsement" section of eNSpect, should at a minimum include a general discussion of the complaints that were covered and the complaint number(s). The complaint numbers should be recorded in the endorsement of the OP13/OP15. All FDA complaints requiring coverage during an inspection or investigation will populate in the eNSpect assignment based on the FEI. The consumer complaints tab in eNSpect must be completed for complaint coverage and suggested follow-up disposition when FDA complaints are listed.

Investigations (OP13 or OP15) covering complaints must only contain one FEI and have the investigation basis of consumer complaint.

The time spent on the consumer complaint follow-up should be reported in the eNSpect assignment (OP13 or OP15) under the appropriate complaint Program/Assignment Code (PAC) for any complaints covered during the investigation. Refer to the PAC Master List for the appropriate PAC.

If a sample is collected during a domestic consumer complaint follow-up investigation, the sample number is linked to the OP13 in eNSpect by entering the sample number under the "Details" page in eNSpect. In addition, an OP31 (Sample Collection) with a collection report containing all relevant information will be completed. If the primary response to the complaint is collection of a sample and no further investigation, no assignment (OP13 or Op12) is generally created for completion in eNSpect. In this case all relevant documents would be included with the OP31 collection report.

8.1.9.4 - Reporting information obtained from a confidential source

During an investigation, inspection, or other operation, you may acquire information from a confidential source. See IOM 5.4 for information on how to interview confidential source and document information obtained from them. Information received from a confidential source during an investigation should be captured in an investigation memo as an attachment to the OP13/OP15. See IOM 5.4 for suggestions on how to protect the identity of the confidential source when writing your investigation memo. Information contained within an OP13/OP15 is outside the scope of FMD-145 (Release of the Establishment Inspection Report (EIR) and should be reviewed by FOIA personnel for appropriate action before release.

If during an inspection you interview a confidential source or whistleblower, do not include any identifiable information in the EIR and prepare a separate memo of investigation to cover this part of the inspection. Enter as an OP 13 or OP 15. See 5.4.

8.1.9.5 - Reporting investigations conducted during disaster response

There is no prescribed format for narrative reporting of disaster operations. Consult with your supervisor as to your division's preference. If operations were conducted as an investigation, you will likely write an investigation memo to document the activities. The memo should briefly describe the onset of the disaster, its magnitude, and your activities. Include cooperation with officials, planning operations, and the logical sequence of your activities.

Your memo must contain exhibits consisting of photographs, diagrams, records, references to samples, and any other items necessary for proper presentation of the operation. Refer to RPM Chapter 8 "Emergency Procedures," for guidance on reporting natural disasters and civil disorders. List amounts of materials or products destroyed and the method of destruction. Prepare charts and lists as necessary to provide documentation of all affected lots destroyed, reconditioned, or released. Include kinds and amounts of materials segregated, released, reconditioned, and destroyed and method of reconditioning and/or destruction.

In situations where an ICS structure has been implemented, operations are reported through the IMT and use of ICS forms, situation reports, after-action reports, or other documents as appropriate to the operation. The IMT will direct you on reporting your time spent working on the operation. If a sample of an FDA-regulated product is collected as part of the disaster response under ICS, an OP31 (Sample Collection) with a collection report containing all relevant information will usually be completed. In this case, your time spent conducting the sample collection would be reported in FACTS as part of the OP31 and using the PAC appropriate for the assignment.

8.2 - Human and Animal Food Investigations

8.2.1 - Coordination

The initial step in coordination of a human and animal food investigation is notification of the potential incident. Notification to FDA may be received from SLTT officials via the district ERC or divisional staff; consumer complaints or adverse event reporting portals; or from federal entities such as the Centers for Disease Control and Prevention (CDC) alerting the FDA of illness clusters. Regardless of the source, once a potential incident is identified, the district ERC (DERC) is the primary point of contact (POC) for coordination of the response at the field level. (See Communications SOP for ERCs)

If agency-level central coordination is needed, CORE or CVM will most often provide management of the incident based on whether human or animal foods are suspected. However, there are instances when food incidents may be coordinated by OEM or a CFSAN office based on the specific commodity and scope of incident. *(See Exhibit 4 for the "Table Depicting Incident Coordination Body by Type of Incident.)*

8.2.2 - Foodborne Illness Outbreak Investigations

8.2.2.1 - Cooperation with Other Agencies

One of FDA's functions is to assist SLTT and other federal agencies in conducting investigations, collecting samples, and conducting firm inspections if warranted.

In addition to state and local health departments, the following federal agencies may also become involved in investigating foodborne disease outbreaks:

- Centers for Disease Control and Prevention (CDC)
- U.S. Department of Agriculture (USDA)
- Environmental Protection Agency (EPA)

CDC becomes involved in foodborne outbreaks when people in more than one state are sick with the same germ from contaminated food. Their role involves coordinating the epidemiologic investigation, including identifying illnesses. CDC works directly with CORE to provide epidemiological information to help identify a possible food vehicle and focus the scope of FDA's investigation. During an outbreak, CORE and CDC coordinate with internal and external partners (including international governments) to help determine the outbreak source and prevent future illness.

USDA is responsible for investigating outbreaks involving meat and poultry products under their jurisdiction. Whenever a complaint is received involving any meat-containing product, including such items as soups, combination infant foods, frozen dinners, etc., evaluate the need to contact

USDA. Most products containing red meat or poultry are regulated by USDA. The exceptions include:

- products containing meat from game animals, such as venison, rabbits, etc.
- meat-flavored instant noodles
- "pork and beans" (which contains only a small amount of pork fat and is regulated by FDA)
- Closed face sandwiches

USDA-regulated products display on their labels a round "shield" with the USDA Establishment Number. Alternatively, the establishment number may be identified in the lot number. Red meat products under USDA jurisdiction will often contain the abbreviation "EST" followed by a one to four-digit number; poultry products under USDA jurisdiction will contain the letter "P" followed by a number.

IOM 3.2.1 and 3.2.4.3 provide information for reporting suspected outbreaks to USDA and CDC. In addition, FDA and CDC have an agreement that FDA will be immediately advised whenever CDC ships botulism antitoxin anywhere in the United States or its possessions.
Whenever a water source is suspected as a likely origin of the agent of an illness outbreak, the EPA should be notified. For example, when investigating a foodborne outbreak on a vessel passenger conveyance, you may find the water used in food preparation to be from a land-based source or from an on-board water treatment plant. Both of these sources would fall under EPA jurisdiction. See IOM 3.2.11.

When two or more people get the same illness from the same contaminated food or drink, the event is called a foodborne illness outbreak. For more information related to foodborne illnesses, please refer to https://www.fda.gov/food/recalls-outbreaks-emergencies/outbreaks-foodborne-illness

8.2.2.2 - Outbreaks on Foreign Flag Vessels

If a suspect outbreak involving a foreign flag vessel or a U.S. flag vessel with an international itinerary comes to your attention, report it to your supervisor and the district ERC immediately. The district ERC will provide the information to OEM/OEO. The CDC assumes primary jurisdiction for foreign flag (non-U.S. registry) and U.S. flag vessels with international itineraries entering the U.S. and traveling in U.S. waters. See IOM 3.2.4.3.

8.2.2.3 - Outbreaks Involving Interstate Conveyances

Reports of illness attributed to travel on an interstate conveyance (plane, bus, train, or vessel) are a shared responsibility of FDA, CDC, USDA, EPA, and potentially others. When a report of illness is received, notify the district ERC in your division/district. The ERC will contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov. Please include the CFSAN Office of Food Safety Interstate Travel on any email correspondence (Joseph.morin@fda.hhs.gov). In addition, you are encouraged to share the report with state and local public health officials. The following activities are to be coordinated with local/state public health officials: Interviews with the ill passenger(s), family members (well and ill), caregivers, and/or health professional (as appropriate) should be sufficiently probative to hypothesize if the food, water, or an environmental transmission is related to the

illness. Transmission of illnesses, particularly viral diseases, by ill employees and contaminated environmental surfaces can result in illness carryover between successive trips and should be considered. Factors such as symptoms, time of onset of symptoms, food history for the 72 hours prior to onset of the first symptom, any clinical laboratory results, and other potential exposures should be documented. The carrier should also be contacted to determine if other reports of illness have been received (passengers and employees). Obtain any illness logs from the carrier. The information developed should be evaluated to determine if further follow-up is necessary. On those carriers where a reservation system is used, obtain the names and phone numbers of passengers, and a passenger manifest, if available. If a reservation system is used, then a passenger manifest should also be available. A manifest will provide passenger seating, which will help identify additional cases based on proximity or in the event of an etiological agent like Norovirus, the passengers who occupy the seat on the next flight could also be at risk of infection. It may be necessary for the state/local health authorities, CDC or FDA to contact other passengers to determine if they became ill.

If additional cases are uncovered during these contacts, immediately notify the appropriate ERC in your division who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov and the state and local public health authorities in all of the affected states. FDA will work cooperatively with these authorities and request their assistance in conducting an epidemiological investigation and collecting patient specimens. Note: If at any time the local/state public health officials are unable to assist with an investigation, have the district ERC notify CORE Signals Team at CORESignalsTeam@fda.hhs.gov who will contact the CDC and request assistance with the epidemiological investigation.

8.2.2.4 - Outbreak Management

CORE coordinates FDA's efforts to prevent, detect, investigate, respond to, evaluate, and apply lessons learned from foodborne outbreaks and public health incidents. Along with ORA, CFSAN subject matter experts (SME), and others in FDA, CORE manages the strategy and implementation of outbreak response activities and evaluates environmental, epidemiologic, and laboratory data to inform assignments and direction of outbreak investigations related to foods, cosmetics, and dietary supplements. ORA's primary role in the outbreak investigation is to perform activities related to tracing food from source to destination; food and environmental sample collection and analysis; and facility investigations.

If you become aware of a foodborne outbreak, contact the appropriate district ERC immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

8.2.2.5 - Conducting Foodborne Illness Follow-up

A priority for all foodborne illness investigations is to establish the basis for implementing control measures to stop transmission and prevent additional illnesses.

CDC is the federal agency with primary responsibility for investigating large, multi-state foodborne illness outbreaks. FDA plays a role in outbreak response generally by collecting samples, obtaining traceback information, and conducting food establishment inspections. CDC guidance for

investigating foodborne illness is available at Investigating Outbreaks (https://www.cdc.gov/foodsafety/outbreaks/investigating-outbreaks/index.html). SLTT generally conducts small, local foodborne illness outbreaks using generally the same process. In FDA, CORE guides investigations into the cause of foodborne illness outbreaks after notification from CDC that an outbreak is ongoing.

A resource for conducting epidemiological investigations is the *Council to Improve Foodborne Outbreak Response* (CIPHOR). Its website (https://cifor.us/) has many resources available to aid during an epidemiological investigation.

If you receive a report of a foodborne illness or an outbreak provide details to your district ERC and determine the extent of investigation you need to conduct. If you are required to respond to a foodborne illness outbreak use the following as guidance.

8.2.2.5.1 - Preparation

Divisions should maintain enough supplies of equipment used for sampling during a foodborne illness investigation. Assure all sterile supplies are within expiry. It is important that swabbing materials be monitored and utilized in a first in, first out manner to prevent the expiry of supplies.

8.2.2.5.2 - Interviews

Reports of foodborne illness can come from many sources, such as:

- Laboratories
- Hospital-based laboratories
- Clinical laboratories
- National or regional commercial referral laboratories
- Local or state health department laboratories
- CDC laboratories
- Health care institutions
- Hospitals (e.g., hospitalized patients reported by infection control practitioners)
- Emergency departments
- Long-term–care facilities or nursing homes
- Physicians
- Schools and childcare centers
- Food establishments (e.g., restaurants)
- State health departments

Regardless of the source of the report, the diagnosis must be verified by a thorough case history and, if possible, by examination of appropriate food samples and clinical specimens.

8.2.2.5.2.1 - Conducting Interviews

Normally, conducting foodborne illness interviews is not a role CSOs will perform since food history/symptoms are typically gathered by CDC and/or SLTT partners. Follow the guidelines upon contacting the affected person in the General Interview section (Section 8.1.6.1) of this chapter and the following:

- Identify yourself and explain the purpose of the visit or call.
- Ensure confidentiality.
- Conduct interviews in a private location.
- Be non-judgmental.
- Show empathy and attempt to build rapport with the interviewee.
- Exhibit genuine concern for persons affected and be sincere and respectful when requesting personal and confidential information.
- Set your level of communication based on the person being interviewed.
- Be tactful. People are sometimes sensitive to questions about age, gender, special dietary habits, ethnic group, excreta disposal, and housing conditions. Phrase questions thoughtfully.
- While keeping the interview as conversational and as natural as possible, communicate a sense of urgency and emphasize the positive contribution already made by the interviewee toward the control and prevention of foodborne illness.
- Use open-ended questions.
- Phrase your questions so the interviewee(s) will describe their illness and the foods and events which they feel are associated.
- Accurately record what interviewees say.
- Gently redirect, as needed.
- Probe if answers are vague, particularly about time of symptom onset.
- Asking references may help their memory, for example, “What did you do prior to eating lunch?”
- Work with epidemiology staff to provide language interpretation, if needed.
- Thank interviewee at closing and explain how the information will be used.

8.2.2.5.2.2 - Information to Gather

Targeted, effective and pertinent information gathering is critical in a foodborne illness outbreak investigation. Per the CDC: Health officials use three types of data to generate hypotheses about the likely source of an outbreak: epidemiologic, traceback, and food and environmental testing. Investigators begin by trying to pinpoint how the pathogen spread. They review details such as:

- The specific pathogen causing illness
- Where sick people live
- How old they are, their sex, and race/ethnicity
- Did they have contact with a sick person

When a contaminated food is suspected, investigators must consider many different foods that may be causing the illness. Interviews help to establish a list of foods people ate before getting sick and collect information on other exposures such as restaurants where the ill person ate and stores where they bought food. This list is used to help investigators determine what food or ingredients the sick individuals may have in common.

Consult with management, ERCs, CFSAN, SMEs, state liaisons, state partners, FDA, CORE, and others involved in the outbreak, as necessary, to determine what information is needed from the interviewee(s). Interview topics can include:

- Interviewee information
- Clinical information
- A standard list of food items
- Each meal a person ate before becoming ill and all meals and snacks eaten seventy-two hours before onset of illness. The food, even the meal, which precipitated the illness, might not be obvious and the type of illness will sometimes provide clues:
  - If the first and predominant symptoms are nausea and vomiting, concentrate questions on foods eaten recently.
  - If the first and predominant symptoms are diarrhea and abdominal cramps, foods eaten six to twenty hours before onset of illness are suspect.
  - If diarrhea, chills, and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.
  - More unusual illnesses often present different clinical patterns. For instance, some illnesses such as Typhoid Fever and Hepatitis A, have incubation periods greater than 72 hours.
- Food allergies, special diets, vitamins, and supplements
- Sources of food at home/outside of the home
- Animal contact and pets
- Specific food categories
- Food shopping habits
- Travel
- Restaurant dining
- Attendance at events where food was served

Although some may not have been ill, use this detailed interview approach with each individual identified in the initial complaint or alert, until there is sufficient information to determine the scope and source of the foodborne illness outbreak.

8.2.2.5.3 - Medical Records

Physicians' and hospitals' records can be useful in verifying reported signs, symptoms and other clinical data and can sometimes rule out the possibility of foodborne illness. See General Section on Medical Records (Section 8.1.6.2).

8.2.2.5.4 - Sampling Procedures

CAUTION: Never taste any of the food products. Handle all samples with caution to prevent accidental exposure to and/or ingestion of even minute amounts of the contaminated or suspect product.

8.2.2.5.4.1 - Sample Collection

During investigations of foodborne illnesses, cooperate with other public health officials in collecting samples of items that may be associated with the outbreak.

Use interview information and a menu or data from an attack-rate table to determine which of the foods from the implicated meal are most suspect and collect samples of the suspect foods. Check storage areas for items that may have been overlooked. Check garbage for discarded foods or containers. Suspect foods often are discarded by an operator if he thinks someone may have become ill as a result of eating in his establishment. Because one of the primary tasks of the investigator is to prevent further illness, take appropriate action to prevent distribution or serving of any suspect food. If no foods remain from the suspect meal or lot, try to collect samples of items prepared in a similar manner, but subsequently to the suspect lot. Collect ingredients or raw items used in the suspect food. Determine supplier, distribution, and code information on ingredients and packaged foods to aid any investigation of the same lot in distribution channels.

Collect samples aseptically. If foods are to be examined for organophosphate pesticides or heavy metals, do not use plastic containers. Use glass jars with foil-lined lids because substances from the plastic can leach into the food and interfere with analysis.

The following are examples of articles normally collected:

- Remaining portions of all suspect foods.
- Parent stocks of suspect foods.
- Insecticides, rodenticides, or other poisons which may be involved.
- Suspect food containers such as cans, bottles, etc.
- Utensils or materials used in the preparation and storage of the suspect food.
- Table scrapings and food residues from equipment such as slicing machines, cutting boards, etc.

NOTE: Clinical specimens such as vomitus, stools, swabs of nasal and throat passages, or open sores or lesions of food workers are collected by local, state, or CDC health officials or private physicians. Do not collect these samples.

8.2.2.5.4.2 - Sample Size

In general, follow the IOM SAMPLE SCHEDULE in Charts 1, 2, and 3 (IOM, Chapter 4). Where only small amounts of items remain, such as partial meals/leftovers, empty containers with adhering particles, etc., collect all or as much as possible by scraping from utensils, equipment, or containers. It may also be necessary to collect the empty containers.

8.2.2.5.4.3 - Sample Handling

Record the temperature of the room, refrigerator, or warmer in which the food was stored, and the temperature of the food that remains after a sample is collected.
Inform the laboratory of the type and number of samples. Discuss methods to preserve and transport samples, time of arrival, and the person who will receive the shipment.
Follow guidance in Chapter 4 for collecting, handling, and shipping samples. See IOM 4.7.5.6.

If the suspect food is a commercial product, examine the original package or container for coding information to identify the place and time of processing. Your division may notify all

agencies responsible for regulating the products alleged or suspected to have caused the illness. Collect additional packages bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum, leaks, or other conditions. Be as specific as possible in requesting the type of analysis.

8.2.2.5.5 - Establishment Investigation

After a foodborne illness outbreak is reported and an investigation is initiated, the initial impact of the incident can create confusion at the facility and could result in conflicting information if too many entities become involved.

The responsibility for investigating foodborne illness outbreaks rests on a core team of people who each contribute different knowledge and skills. For FDA-initiated investigations/inspections, one FDA investigator should be designated as the inspection team leader. The team leader will set and enforce priorities, coordinate all activities associated with the investigation, serve as the point of contact about the investigation, communicate with other organizations involved in the investigation and communicate the recommended course of action determined by team to ORA management. A supervisor and/or ERC should be the coordinator for overall division activities and the division contact for headquarters personnel. All communications from FDA field or other offices to the firm's management should be channeled through the supervisor/ERC. The lead investigator should be responsible for all phases of the physical inspection of the facilities and briefing the supervisor about team progress. See IOM 5.4.

Upon arrival at the establishment where the suspect food was processed or prepared, identify yourself to the person in charge and state the purpose of your visit. Emphasize the purpose of the investigation is to determine what contributed to the outbreak, so preventive measures can be taken. Attempt to create a spirit of cooperation. Consider the position, feelings, and concerns of the manager and facility staff; defensive reactions are common.

Many factors could have contributed to contamination before foods came under the control of the manager. Assure the manager that these possibilities will be investigated. Inform the manager of the activities proposed and benefits gained for educating their workers.

When investigating the root cause of the contamination obtain the following documents: inspection reports (state and/or federal), detailed epidemiological data and traceback investigation reports to try to pinpoint locations of interest, environmental monitoring records, verification records of the identity, safety, strength, purity, efficacy, and accuracy of raw materials and packing materials used, and any analysis of resource availability, (e.g., documenting sufficient manpower and prescribed raw materials, packaging materials utilized, substitutions made, etc.), and historical data on weather events, e.g., flooding, for foods produced in the open outdoor environment.

Perform the following activities:

1). conduct personnel interviews to determine their qualifications, knowledge, experience, and training;

2). review related logbooks, records, processes, laboratory data;

3). document observations made with photos and videos whenever possible;

4). visit the facilities or farms, where causes of the event occurred (where possible).

5) Describe the processes, equipment, and facilities.

6) Evaluate the following: the suitability of equipment, facilities, and utility systems; the calibration and preventative maintenance of the equipment and instruments used; the adequacy and the implementation of the relevant standard operating procedures (SOP) utilized by the food business operator; and the Good Manufacturing Practices (GMPs), preventive controls and food safety standards, as applicable, utilized in the area where the product concerned was produced, processed, packed and/or held.

Include all relevant information in the investigation memo or EIR as appropriate.

Review of distribution records and examination of warehouse stock are two important aspects of a foodborne illness follow-up inspection. Field examination should include an inventory by code of all stock on hand. When conducting field examinations, follow instructions in IOM Sample Schedule Chart 2 (IOM, Chapter 4).

8.2.2.5.5.1- Food Handlers Interviews

If a food is already suspect, interview separately all persons who were directly involved in processing, preparing, or storing of the food and others who could have observed preparation and storage. Ask questions in a sequence that discloses the flow of food from the time it was received until it was served or distributed. Especially inquire about foods that were prepared several hours or days before being served with the suspect meal and about foods that have specific temperature requirements. Ask similar questions, suitably modified, of the managers or workers who were involved in producing, transporting, processing, preparing, or storing food at other levels of the food chain, as well as individuals who prepared the food at home.

Food workers who fear criticism or punitive action because of their possible role in the outbreak do not always accurately describe the food handling as it actually happened. Their descriptions should be plausible, account for possible sources of contamination, and indicate possibilities of survival and potential for growth of pathogens. If the description does not contain all the information desired, rephrase the questions and continue the inquiry. Seek confirmation of one person's story by talking to others who have knowledge of the food operation, or by watching the food preparation or processing practices. Be alert for inconsistencies among the accounts, as told by different individuals.

8.2.2.5.6 - Possible Contamination Source

It is important to understand the pathogen and the factors that contribute to the contamination that resulted in the foodborne illness. Some pathogens, such as Norovirus, are associated with

human fecal contamination, while other pathogens, may be more commonly associated with a particular food source (e.g., raw meat and E. coli O157:H7).

CDC has identified the most common causes of foodborne illness:

- Food from unsafe source.
- Poor personal hygiene.
- Improper food holding temperatures.
- Improper cooking temperatures.
- Contaminated equipment of cross-contamination of raw with ready-to-eat foods

You may want to familiarize yourself with Factors that Contribute to Outbreaks of Foodborne Illness (https://www.cdc.gov/nceh/ehs/nears/factors-contribute-to-outbreaks.htm) before beginning a foodborne illness investigation.

Exhibit 8-5 (https://cifor.us/uploads/resources/CIFOR-OUE-Agent-List_FINAL.pdf) provides details about possible food associations with different illness symptoms, latency and factors that contribute to outbreaks. Although the table lists possible clinical specimens to collect, you should not collect clinical samples. A SLTT health department may be able to assist and collect those samples for analysis at a state laboratory.

8.2.2.5.7 – Conducting Traceback Investigations

Traceback investigations are important epidemiological tools that are used to determine the source of food implicated in foodborne outbreaks. Traceback investigations may prevent further sale and distribution of contaminated food. Commonly, SLTT agencies conduct the initial epidemiological investigation of foodborne outbreaks and identify suspect product(s) requiring tracebacks.

CORE issues traceback assignments to the appropriate division(s) and coordinate inter-division assignments for traceback investigations. The assignment will generally provide all the guidance needed to conduct the traceback investigation.

Other resources available include:

- the FDA *Guide to Traceback of Fresh Fruits and Vegetables Implicated in Foodborne Outbreaks*, dated April, 2001
- the Office of Training Education and Development (OTED) training: *ER220: Traceback Investigations*.

8.2.2.6 - Reporting

8.2.2.6.1 - Reporting Epidemiological Investigations

Follow the reporting guidance in this chapter to report epidemiological investigations. Promptly submit a complete narrative of the investigation, including references to exhibits, samples, medical records, and laboratory reports. There is no prescribed reporting format, but it should be in a logical order. With the inclusion of investigative memos in eNSpect EIR, eNSpect can be utilized to prepare these memos. See the eNSpect EIR Quick Reference Guide for detailed information. See also IOM 8.10.

Submit copies of any written reports and documents for all injury or illness complaints involving all CFSAN products (see section 8.2 and 8.4.5) using encrypted email, secure fax transmission, or mailing.
If using mail, use this address:

Food and Drug Administration
CFSAN/OSAS
CAERS Staff (HFS-700)
5001 Campus Drive
College Park, MD 20740
Attn: CAERS Monitor

Illness/injury complaints involving special nutritional products (refer to IOM 8.2.3.2) must be accompanied by a CMS Complaint with Adverse Event Section completed when forwarded to CFSAN.

If additional follow-up on any complaint involving a CFSAN product is necessary, the Division of Field Program Planning and Evaluation (HFS-635) will issue an assignment.

8.2.2.6.2 - Reporting Food Adverse Events

Prompt reporting is essential. You may save the lives of others with prompt reporting. If consumers contact you to report adverse events including injury, illness, or death related to a human or animal food, dietary supplement, or cosmetic, they should be directed to report through the following online reporting systems. If they do not want to report through those systems, you may report for them.

8.2.2.6.2.1 - Food and Cosmetics

Details on reporting adverse events related to human food can be found at the CFSAN Adverse Event Reporting System (CAERS) website (https://www.fda.gov/food/compliance-enforcement-food/cfsan-adverse-event-reporting-system-caers).

8.2.2.6.2.2 - Dietary Supplements

Details on reporting adverse events related to dietary supplements can be found at the How to Report a Problem with Dietary Supplements website (https://www.fda.gov/food/dietary-supplements/how-report-problem-dietary-supplements).

8.2.2.6.2.3 - Cosmetics

Details on reporting adverse events can be found at the How to Report a Cosmetic Related Complaint website (https://www.fda.gov/cosmetics/cosmetics-compliance-enforcement/how-report-cosmetic-related-complaint).

8.2.2.6.2.4 - Veterinary Products

Details on reporting adverse events and complaints for animal food and animal medical products can be found at the CVM Report a Problem website (https://www.fda.gov/animal-veterinary/safety-health/report-problem).

8.2.2.6.2.5 - Reports of Criminal Activity

If a consumer calls to report criminal activity, they should be directed to the Report Suspected Criminal Activity website (https://www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm).

8.2.3 - Injury, Illness, Death

Injury, illness, product defect, and adverse reaction complaints should receive a prompt, courteous response, and assurance their complaints will receive appropriate consideration. Complaint Escalation must be done when there is an indication of a life threatening injury or adverse reaction, per SOP-000544.

When you are investigating injuries or adverse reactions, do not make comments or enter discussions with firms as to the involvement of particular products, unless specifically instructed to do so. Many adverse reactions come to FDA from consumers or health care professionals through the voluntary reporting branch of the MedWatch system. Complainant name, address, and contact information should always be kept confidential, unless express permission is given by the complainant to share it.

Whenever the press has been informed about a complaint, follow instructions found in Section 1.6.1. When the responsible firm invites the news media to observe the inspectional process, follow instructions found in Section 5.1.4.3.

NOTE: CFSAN Adverse Events Reporting System (CAERS) Staff, HFS-845, 240-402-2405, Fax: 301-436-2452, or email CAERS@fda.hhs.gov, can assist with questions pertaining to field follow-up related to foods, seafood, food additives, dietary supplements, infant formulas, and medical foods. CAERS personnel can assist in obtaining guidance from CFSAN's experts.

8.2.3.1 - Procedures

When investigating all injuries and adverse reactions the consumer complaint coordinator will follow *SOP-00045 Consumer Complaint Procedure*.

Once it is determined by program management that follow-up is deemed necessary, an assignment will be created and assigned to a CSO, who will then fill out the Follow-up Consumer Compliant Report in FACTS.

The following should be addressed and confirmed during a follow up investigation with the complainant.

- Details on the product involved, including brand name, product labeling, and any codes including lot, expiry, and/or use by codes.
- The source of the product. Where did the consumer obtain it?
- Details of how the product was used, including frequency, in what amounts, any known previous adverse reactions or pre-existing allergies and whether anyone else used the product in the household.
- If appropriate, determine if label directions were followed.
- Copies of all labeling/inserts.
- Any research the complainant may have conducted or relied upon and collect copies or internet web addresses.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location, and symptoms or description of injury.
    - Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.
    - Photographs of the victim's injuries, if significant. See Section on Medical Records.
- List names of other persons involved, such as beauty salon operators, medical personnel, lawyers, insurance agents. Obtain their views on the injury or adverse reaction. The views of an attending physician are important because they may vary markedly from those of the patient.
- Determine if the consumer reported the adverse reaction to the manufacturer and the manufacturer's response.
- Any other consumer complaints, injuries or alleged adverse reactions reported to the manufacturer concerning the product.
- If necessary, obtain distribution information of the implicated lot(s) from the manufacturer.

8.2.3.2 - Specific Product Reporting (Food, Dietary Supplement, and Cosmetic – Injury or Reaction)

8.2.3.2.1 - Dietary Supplements

It is extremely important that FDA conducts appropriate investigations and follow-up on adverse events attributed to dietary supplement products. DSHEA removed dietary supplement and ingredients from food additive regulations and therefore it is the agency’s burden to prove them unsafe. An important source of information concerning potentially unsafe dietary supplements and ingredients is consumer complaints.

Injuries or other adverse reactions may be associated with the use of products which:

- Vary from the declared potency or concentration.
- Contain deleterious substances accidentally included in manufacturing.
- Have changed composition or become contaminated after shipment.
- Are mislabeled as to identity warnings or instructions for use.
- Have not been used according to label instructions or the directions of the manufacturer or prescriber.
- Are dangerous when used according to directions.

When investigating adverse events attributed to dietary supplements, direct attention to, and document:

- Details on the product involved, including lot codes and expiration dates.
- Source of the supplement. Where did the consumer obtain it?
- Details on the consumer's use of the product including frequency, dose used, concomitant treatments, and whether administered by the user or someone else.
- Details on the directions of use provided with the product or otherwise (on the web or from a practitioner). Obtain copies of labeling and any additional information concerning use of the product by the consumer.
- Nature of the injury. Include any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury. Obtain photographs of the victim's injuries, if significant. See IOM 8.1.6.2 for the procedures used to obtain medical records.
- Names of other persons involved, such as medical personnel, lawyers, insurance agents, etc. Obtain their views on the injury. The views of the attending physician are important because they may vary markedly from those of the patient.
- Complete description of the incident (sequence of events) and the nature of the injury or adverse reaction, including date, time, location and symptoms or description of injury.
- Any hospital or physician's records available and identify pre-existing conditions which may have a bearing on the injury or adverse reaction.

Photographs of the victim's injuries, if significant. See Section on Medical Records

8.2.3.2.2 - Cosmetics

For clarification of the distinction between cosmetics and drugs, refer to the document, "*Is it a cosmetic, a drug or both? (or is it soap?)"* located at https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap

If you are unsure about a products status, you may contact the Office of Cosmetics and Colors at (240) 402-1130.

8.2.3.2.2.1 - Causes

Injuries or adverse reactions may arise from cosmetics which:

- Are inherently dangerous or which may prove harmful or injurious to a consumer.
- Cause primary irritation of skin, eye, or mucous membranes (including the lungs and urinary tract) or which may be due to an individual sensitization reaction or allergic response, or due to ingestion.
- Have undergone formulation changes or been chemically or microbiologically contaminated while in the possession of the manufacturer, dealer, distributor, or end user.
- Are misbranded because they contain unlisted ingredients, lack instructions for safe use for certain high-risk products (e.g., depilatories, hair dyes), or lack any required warning statements.

- Have been misused.

8.2.3.2.3 - Investigation Requirements for Serious Adverse Events of CFSAN Regulated Products

If the suspect product is a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Consumer Complaint Cosmetic Report. If the suspect product is not a cosmetic, interview the injured person and/or the reporter of the event and complete the FACTS Adverse Event Questionnaire.

If the suspect product is an infant formula or baby food, immediately inform OEM/OEO at 866-300-4374 or Emergency.Operations@fda.hhs.gov and investigate on a high-priority basis due to the continued sensitivity to these incidents. This will include follow-up with the doctor or hospital, sample collection, and analysis of appropriate product. Refer complaints involving baby food regulated by USDA for appropriate follow-up. See IOM 8.1.8.1 and 3.2.1.2.

Obtain Medical Records as described in Section 8.1.6.2.

If the adverse event is a death, the following medical records should be considered for collection:

- Admission history and physical or emergency room/clinic record of the event if the patient was not admitted
- Discharge Summary
- Autopsy Report
- Death Certificate

If you believe a suspect product should be sampled, discuss with your supervisor.

For all events, a memo of investigation will be completed. Send a complete copy, including copies of all labels and labeling, Medical Records Letter [IOM Exhibit 8-4] and medical records collected to the CAERS Staff.

8.2.3.2.4- Undeclared Allergen/Allergic Reactions

Suspected undeclared allergen complaints should receive high priority. Undeclared allergens in food products often result in recalls.

The following should be addressed and confirmed during a follow-up investigation with the complainant:

- List all the complainant's food allergies.
- List all foods consumed within approximately an hour prior to reaction.
- Amount of suspect food consumed.
- Time of on-set.
- Specific symptoms experienced and the order they occurred.
- Medical or other treatment received.
- The ingredient statement from product packaging.

- Any label statement related to a "may contain" statement and record the statement.

Inspectional follow up at the manufacturing plant may be warranted to determine if suspect allergen is added to the product; or if the possibility of cross-contact exists.

8.2.3.3 - Veterinary Products-Complaints/Adverse Reactions

If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

Investigations of complaints of animal food, both medicated and non-medicated, should be investigated like other complaints. Discuss any investigation with your supervisor. The CVM Office of Compliance can be consulted concerning appropriate follow-up and sample collection related to complaints.

8.2.3.4 - Sample Collection

When directed to collect a sample, collect the product which appears to have caused the injury and an official sample from both the same and other lot codes, if available. Check with your supervisor if you have any doubt as to the appropriateness of collecting a sample related to an investigation. See IOM 4.7.5.4.1 for routing of injury and complaint samples to the laboratory.

8.2.3.4.1 - Cosmetic Samples

Many cosmetic products such as permanent hair dyes, home permanents, deodorants, hair straighteners, etc. are known to cause adverse reactions. Samples of these products should not be collected except in cases of alleged severe or unusual injury (e.g., multiple complaints). In cases of obvious allergic type reactions, samples should not be collected. For example, most cosmetic products which get into the eye will cause temporary eye irritation and, in such cases, a sample generally should not be collected.

8.2.3.4.2 - Microbiological Contamination

Collect samples associated with consumer complaints in which microbiological contamination is suspected.

8.2.3.4.3 - Allergen Samples

Collect a sample if the allergen is visible (i.e., nuts,) is not declared on the label, and if deemed necessary by division management. In all other cases, collect a sample only after consultation with OEM/OEO (e.g., national consumer complaint coordinator) and CFSAN. See IOM Sample Schedule Chart 13 for guidance on sample size. Note: the sample size may be modified depending on product availability.

8.2.4 - Special Events

Special Events (SEs) are organized, pre-planned mass gatherings of national or international importance that usually garner significant media coverage and are typically attended by dignitaries or public

personalities. The venues for these events are predominantly large retail food establishments such as stadiums, arenas, convention centers, and hotels which contain retail food establishments that are under the jurisdiction of state and local agencies. SLTTs, United States Secret Service (USSS), or the event organizer may request FDA assistance.

See Special Event Planning Guidance (SEPG).

NSSEs are a select group of SEs that are designated by the Secretary of the U.S. Department of Homeland Security (DHS) to be of significant importance and may be a potential target for terrorists due to the event's visibility or political connection(s). The types of SEs/NSSEs supported by FDA include Presidential inaugurations, major national political conventions, North Atlantic Treaty Organization (NATO) and other summits of geopolitical significance, Olympic Games held in the U.S., and some major sporting events. You may be requested to investigate food suppliers to the SE to verify compliance with regulations. This investigation, referred to as a Supply Chain Integrity Check (SCIC), may be performed onsite or through an online record review.

8.2.5 - Farm Investigations

A farm investigation of a raw agricultural commodity (RAC) may be conducted in response to traceback information obtained during a foodborne illness outbreak investigation that implicates one or more farms, ranches, packing houses, or other such operations as being involved in handling the outbreak suspect RAC. Generally, CORE would request a domestic farm investigation through the district ERC for the responsible ORA Human and Animal Food (HAF) program division office. HAF program division offices may also initiate or be assigned by CFSAN or ORA/OHAFO to perform a farm investigation as needed to protect public health. The goals of a farm investigation are to gather information, to identify potential environmental sources of the outbreak agent, to identify routes of contamination from potential outbreak agent sources to the implicated RAC, to observe and document potential contributing factors to the outbreak such as practices, procedures, or conditions that may facilitate proliferation, spread, growth, survival, or contamination by the outbreak agent, and to support regulatory action, if appropriate.

8.2.5.1 - Approach

A team approach is utilized for a farm investigation (see IOM 5.2.8 Team Investigations). A lead CSO should be identified from the Produce Safety Network (PSN) or the responsible HAF division office that has attended both the FD226 Produce Inspections for Regulators Course, and the FD326 Produce and Sprout Investigations for Regulators Course. A minimum of three team members should participate and ideally all members should have produce farm training and/or produce farm inspection experience. The appropriate state regulatory agency having jurisdiction over produce farms should be notified and invited to participate. Additional SMEs may be added to provide needed expertise such as wildlife, soils, agricultural water, or epidemiology. CORE, CFSAN Produce Safety Staff, and/or ORA HQ may assist with identifying appropriate SMEs and providing technical guidance during the investigation.

The implicated grower should be notified in advance of the investigation as he/she or a representative of the grower will need to be present to provide information to assist the

investigation. Generally, an FDA 482 will be issued to the grower or packing house, if different. If the investigation expands to fields not owned by the grower, a new 482 must be issued to those growers. Please see IOM 5.2.8 Team Investigations for additional information.
CORE has implemented formalized outbreak incident operation processes. The CORE operation guides are available through the inside.FDA.gov website.

8.2.5.2 - Sampling

A variety of environmental samples may be collected during a farm investigation, including environmental swabs and water from both the field and the packing house, and soil and wildlife scat samples from the growing environment. Do not collect human fecal matter unless specifically assigned or pre-approved to do so. In general, FDA laboratories are not prepared to receive human feces.

Instructions for collecting soil and water samples on farm investigations are found in IOM Ch. 4, in the Salmonella Sample Schedule Chart 1, and are also covered in FD326 (Produce and Sprout Investigations for Regulators Training Course). Additional sampling guidance can be found in SOP-001052 (ORA Field Bulletin #30 – Food Program Area – Instructions for Environmental Sampling), and ORA Outbreak Response Field Guide #1 covering E. coli, Listeria, and Salmonella inspections and investigations at sprout operations. Specific sample collection instructions or methods may also be included in the CORE farm investigation assignment.

All environmental samples are investigational. Use the product code builder to identify the proper code for the type of environmental sample collected, including swabs, soil, water, and animal scat. Do not use the product code of the implicated produce for environmental samples. Produce samples collected from the field or prior to packing (i.e., not finished product) are labeled as investigational. Product that has completed processing on the packing line are labeled official product samples.

8.2.5.3 - Form 3623 Farm Investigation Questionnaire

FDA Form 3623, the Farm Investigation Questionnaire (FIQ), must be completed for all farm investigations, as covered in FD3263. Some portions may not be applicable, such as the use of biosolids. These questions may be marked as N/A. However, questions for practices that may be used but are not currently in use should be completed by use of interview techniques with the grower to the extent possible. The FIQ should be completed on-site to ensure all information is collected and submitted to CORE and/or the CFSAN Produce Safety Staff if requested and included in the Investigation Memo or EIR as an attachment. To avoid duplication, the FIQ may be used to provide information under the “Manufacturing Processes” section by either reference or cutting and pasting into that section. A short summary and flow diagram(s) describing the steps from planting through harvesting and/or packing should be included along with this.

8.2.5.4 - Reporting

Domestic outbreak work assignments will be designated in FACTS as either an operation 12 inspection (OP12) or an operation 13 investigation (OP13). Foreign outbreak work assignments will be designated in FACTS as either an operation 11 inspection an operation 15 investigation.

For FACTS operation 11 or 12 farm inspections see Chapter 5 for reporting; however, if an outbreak is ongoing and the information is needed immediately, it may be necessary to prepare a separate memo to submit to CORE prior to completing the EIR.

For FACTS operation 13 or 15 investigations, follow reporting guidance in this chapter.

8.2.6 - Infant Formula and Baby Food

There is a continued sensitivity to all reported incidents involving infant formula and baby food. All complaints involving either infant formula or baby food are to be immediately escalated following SOP-000544. Appropriate follow-up with the consumer, potential inspection of the manufacturer, and follow-up with the doctor or hospital if appropriate should be done. Samples can be collected as part of the follow-up. Complaints involving baby food regulated by USDA should be referred to USDA for appropriate follow-up. See IOM 3.2.1.2. There are two exceptions for collecting samples as part of the follow-up to infant formula/baby food complaints. Do not collect samples unless directed for:

- Complaints involving outdated product in the marketplace with no associated injury or illness only require investigation to ensure all outdated product has been removed from the identified retail and/or wholesale source.
- Complaints involving an illness associated with normal appearing product when the follow-up investigation discloses that the event does not appear to be product related or was an allergic response to a properly labeled product per a physician's diagnosis. When complaints involving food products intended for infants are received, NOT-000210 should be reviewed to verify if it meets criteria in the memo.

8.2.7 - Tampering Involving Alcoholic Beverages

All tampering complaints involving alcoholic beverages should be entered as a consumer complaint in CMS. OEM/OEO and OCI should be notified immediately following SOP-000544. OEM/OEO can be notified by e-mail at emergency.operations@fda.hhs.gov and by phone 24 hours a day at 1 (866) 300-4374.

For all other complaints involving alcoholic beverages, please see IOM 3.2.8.1 for guidance.

8.3- Drug Investigations

8.3.1 - Investigations Coordination

The following procedures should be followed for investigating suspected adverse drug reactions, including drug-induced birth defects:

- If you are interviewing the consumer, conduct the normal complaint investigation and gather all pertinent information regarding the product, patient, adverse event, etc. If the consumer received medical treatment, obtain a medical records release (Exhibit 8-2). Reporting of drug adverse experiences is voluntary and you should encourage and assist complainants and health care providers to complete the MedWatch form (FDA 3500) (see Exhibit 8-10) and submit to MedWatch. Report your findings in the FACTS Consumer Complaint follow-up screens and in a memo of investigation.

- If you are investigating an adverse reaction at the manufacturer, conduct your investigation to determine whether the adverse event was caused by a drug quality defect. Determine if the manufacturer was aware of the complaint, has investigated, and per IOM 5.14.4 Adverse Event Reporting has submitted the reportable event to FDA. For additional information regarding DQRS (MedWatch Reports) and NDA FARS (New Drug Application Field Alert Report) see the applicable compliance program in the Compliance Program Guidance Manual (CPGM). Determine if the manufacturer is aware of any similar reported events. Collect current labeling of the product to determine whether this was an expected or unexpected adverse event. Your findings will be reported through the FACTS Consumer Complaint follow-up screens and a memo of investigation or EIR.
- You may also be directed to conduct investigations at other establishments, such as pharmacies, doctors' offices, or distributors. Conduct your normal complaint investigation determining each party's role and involvement. If individuals interviewed are not required to report adverse drug reactions, encourage and assist them to complete and submit the FDA 3500 form to MedWatch.

In all cases of suspect drug-induced adverse reactions, the center will review the information on the FDA 3500 form and will issue assignments to the field if additional information is needed.

8.3.2 - Illness/Injury

Drug injuries or reactions, either human or veterinary, result from the use of products which may:

- Vary markedly from declared potency.
- Contain deleterious substances.
- Be mislabeled as to identity, warnings, or instructions.
- Have been mistaken for other drugs despite proper labeling.
- Have changed composition or become contaminated after shipment.
- Be dangerous when used according to directions.
- Have not been used in accordance with label directions or directions from the prescriber.
- Have been improperly administered or administered without the necessary precautions.
- Have been contaminated with objectionable microorganisms, soaps, or cleaning solutions.
- Have been misidentified.
- Be labeled as sterile drugs but are found to be non-sterile.
- Have adverse effects that were not identified prior to marketing.

8.3.2.1 - Reporting

8.3.2.1.1 - Reporting Forms – Drugs

Submit drug complaints and injuries to:

MedWatch
The FDA Medical Products Reporting Program (HFD-410)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Fax Number: 301-827-7241

8.3.2.1.2 - Reporting Forms – Veterinary Products

Submit veterinary injuries or adverse reaction reports to:

Food and Drug Administration
Center for Veterinary Medicine
Division of Surveillance (HFV-210)
7500 Standish Place
Rockville, MD 20857

In addition, follow specific reporting instructions as indicated per an assignment.

8.3.3 - Complaints

The FDA Office of Emergency Management/Office of Emergency Operations (OEM/OEO) HFA-615, 301-796-8240 must be notified immediately of all life-threatening injury/illness, death, and suspected tampering complaints. This may be accomplished by adding the OEO team name to the CMS ORA Consumer Complaint Initial Disposition Decision, per SOP-000544.

- Injury/illness complaints
  - Any illness/injury related to infants should be considered high priority. These complaints are to be thoroughly investigated.
- Complaints and adverse reactions associated with veterinary products including animal drugs, medicated feeds, and medical devices for animals are handled through the FDA CVM Division of Veterinary Product Safety (HFV - 240). Veterinarians, animal owners, and drug manufacturers may report problems to their local FDA district offices or directly to CVM. The division should advise the complainant to complete an FDA 1932a, "Veterinary Drug Adverse Experience, Lack of Effectiveness or Product Defect Report" for drug adverse events associated with unapproved animal and approved human drugs and veterinary devices. For approved animal drugs, the complainant should be instructed to call the manufacturer directly to report the event. Detailed instructions and options for different case scenarios are available at https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm.

For 3-day Field Alert Reports (FAR), drug sponsors now have the option to electronically submit 3-Day field alert reports (FARs) directly to CVM. CVM will receive the electronic 3-Day FAR from the sponsors and will automatically generate and email a .pdf of the FAR with associated attachments to the appropriate district office. Some sponsors may still send the 3-day FAR through the traditional route to the district office. The district office should email the form and any other attachments to CVM. The drug manufacturer should notify and submit the FAR to their respective district office within three days. The district offices will ask for additional information if necessary and submit the 3-day FAR to the Division of Veterinary Product Safety.

Complaints and adverse reactions associated with animal feeds including pet food products are handled through the Division of Compliance (HFV-230) at CVM. Veterinarians, animal owners, and firms may report pet food problems to consumer complaint coordinators at their FDA district office or OEM/OEO; the district will complete a CMS Consumer Complaint Report and follow SOP-000544 for escalation. Pet food reports may also be made directly to CVM using FDA's Safety Reporting Portal. Instructions for stakeholders to report problems associated with pet food products are available at

https://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/default.htm. If you become aware of human illnesses associated with CVM-regulated products, contact the appropriate ERC in your division and/or regional office immediately who will then contact the CORE Signals Team at CORESignalsTeam@fda.hhs.gov.

8.4 - Device Investigations

8.4.1 - Injury/Illness

When investigating incidents implicating medical devices, you must first confirm whether the device was a contributing factor. An appropriate follow-up, such as an inspection at the manufacturer may be necessary. The cause of medical device injuries may originate with the manufacturer, operator, user, or from other factors including, but not limited to, the transportation or installation of the device. Additionally, an illness may occur as a result of device specifications not being met, such as a device labeled as sterile not meeting sterility requirements.

Obtain the following information for medical devices:

1. A complete description of the incident (sequence of events) and the injury/illness, including:
   a. UDI, Type, model, serial number and manufacturer of the device, and copies of any labeling for the specific device(s) involved including instructions for use or operations manual(s).
   b. Details of the alleged incident, including: number of people involved; symptoms, onset time, duration, and outcome; date and time of occurrence; reports of other investigating agencies and their conclusions, (e.g., fire marshal or OSHA reports); similar incidents which may have resulted in injury/illness; and all operational SOPs, written or unwritten.
2. Copies of medical records and/or laboratory records. Use an FDA 461, Authorization for Medical Records Disclosure, IOM Exhibit 8-2, signed by the patient or other authorized person, when obtaining these records.
3. Official cause of death, death certificate, and/or autopsy report, if indicated.
4. Determine if the device malfunctioned, and the cause.
5. The condition of the device at the time of use. Review its maintenance history, including responsibility for maintenance (past and present), special service calls, repairs, whether component warning or safety systems were functional, maintenance records, changes or corrections accomplished just prior to or immediately after the incident, and who performed the activity. An interview with biomedical engineering department personnel may be indicated.
6. Who has access to the device? Determine if individuals using the device are familiar with its operation.
7. The results of any examination or inspection of the device by the hospital or other party to determine the cause of the incident.
8. Whether there are other devices of the same model number or lot number on the premises.

8.4.1.1 - Types of device injuries or illnesses include:

8.4.1.1.1 - Mechanical, Electrical, or Electromechanical Devices

Injuries caused by mechanical, electrical, or electromechanical devices may result from devices that:

- Do not conform to specifications due to mistreatment (e.g., damage in transit), or failure to comply with good manufacturing practices.
- Malfunction due to incorrect installation.
- Have not been used in accordance with labeled instructions.
- Have been used/installed with incompatible accessories or parts which are not compatible.
- Have been used under conditions which interfere with their ability to function (e.g., electromagnetic interference (EMI), fluid seepage into electrical circuits, etc.).
- Have been damaged during use, or random failures.
- Have not been adequately designed for intended use (unstable, poor structural integrity, electrical leakage, reusable but unable to thoroughly clean, etc.).
- Do not contain adequate directions or warnings.
- Are intended to be sterile but are non-sterile.
- Fail or deteriorate for any reason.

8.4.1.1.2 - Devices for Implant

Causes of injuries which may result from implanted devices include those listed in IOM 8.4.1.1.1. An injury or illness may also result because the materials used in the implant are not biocompatible, thereby causing an adverse tissue reaction and/or deterioration of the implant. It is important to obtain information relating to a medical professional's interpretation of the relations.

8.4.1.1.3 - In-Vitro Diagnostic Devices

In Vitro Diagnostics (IVD) are instruments that can include, gas chromatographs and automated blood analyzers, and much of the information under IOM 8.4.1.1.1 is applicable.

Injuries to patients from IVD products may be considered indirect because they are due to complications resulting from misdiagnosis or delays in patient treatment due to incorrect test results. Examples of IVD failures include false positives, false negatives, and erratic results. Poor performance or failure may be due to poor manufacturing practices or user error.

Manufacturing problems include:

- Process errors and mix-ups (varying fill in kit components, improper ingredient addition, etc.).
- Labeling does not contain adequate directions or warnings or contains incorrect information.
- Labeling mix-ups.
- Contamination making the product unusable or causing misdiagnosis.

- User error due to poor directions for use, operator's manual, or inadequacies in labeling requirements.
- Use of unclean, not maintained, or improperly calibrated equipment.
- Improper storage or use of reagents.

For In Vitro Diagnostic devices determine:

1. How the results of the test are used; screening, therapeutic drug monitoring, epidemiological information, monitoring the course of a disease, etc.
2. The role in overall determination of patient clinical care.

8.4.2 - Confidential Sources

FDA may receive external complaints that request their identity to be kept confidential or anonymous. In this case, the complainant's information should not be disclosed in the investigation memorandum or EIR. The complaint should be assessed to determine if it is a non-injury/illness complaint, life-threatening injury/illness complaint, non-life-threatening injury/illness complaint, or death complaint as this may impact the urgency of the response. An immediate follow-up may be warranted if there is illness, injury, death, or if directed by higher authority. All information should be obtained in the least intrusive, yet constructive, manner that allows the investigator to collect the evidence required to evaluate the validity of the complaint to determine if additional action is warranted.

8.4.3 - Complaints

FDA may receive information from various sources, such as a consumer, whistleblower, employee, other governmental agency, Congress, or competitor alleging a potential violation of the FD&C Act that must be followed up to confirm the information provided by the complainant. For medical devices, a complaint means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.

As with all investigation types, report your findings in a memorandum and include all pertinent information and any attachments collected as evidence to support the complaint. Using eNSpect, create an operation 13, domestic investigation, or operation 15, foreign investigation, utilizing only one FEI and the Investigation Basis of Consumer Complaint, and complete all required fields. Upload all labeled attachments and submit for endorsement by your supervisor. Ensure the consumer complaints tab in eNSpect is completed. . If foreign, ensure the center is notified of the investigation and receives a copy of the investigation memorandum and any attachments.

If the complaint is an adverse reaction to a device, advise the complainant to visit FDA.gov, specifically the MedWatch Online Voluntary Reporting Form (fda.gov) to complete an FDA 3500, MedWatch Form; https://www.accessdata.fda.gov/scripts/medwatch/index.cfm (See IOM Exhibit 8-7) and discuss the need to have physician complete the form for submission. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Note in the "Remarks" section of the CMS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant.

8.4.4 - Reporting

The Medical Device Reporting (MDR) regulation and the changes mandated by the Safe Medical Devices Act of 1990 (SMDA) is a mandatory information reporting system. It requires manufacturers, importers, and device user facilities to report to FDA certain adverse experiences caused or contributed to by their devices.

This program is administered by the Center's MDR Policy Team in the Office of Regulatory Programs.

The regulation requires a report be submitted to FDA whenever a manufacturer or an importer becomes aware of information that its device: 1. May have caused or contributed to a death or serious injury, or 2. Has malfunctioned and this device or a similar device would be likely to cause or contribute to a death or serious injury, if the malfunction were to occur.

Under the Safe Medical Devices Act of 1990, user facilities must report device-related deaths to FDA and to the manufacturer, if known. User facilities must also report device-related serious illnesses and injuries to the manufacturer, or to FDA if the manufacturer is unknown. In addition, SMDA also requires user facilities to submit to FDA, on an annual basis, a summary of all reports submitted.

The CDRH Division of Industry and Consumer Education (DICE@fda.hhs.gov) and the MDR Team (MDRPolicy@fda.hhs.gov) in the Office of Regulatory Programs should be contacted for further guidance about the MDR regulation.

As of August 2018, the agency's Voluntary Malfunction Summary Reporting program was implemented. It permits certain manufacturers an alternative method to submit MDRs for eligible product codes in summary form on a quarterly basis; see 83 FR 40973.

8.4.5 – Medical Device Sampling

Obtain CDRH and WEAC concurrence prior to collecting any medical device samples.

8.5 - Biologics Investigations

8.5.1 - Illness/Injury

Reactions or symptoms of illness may occur in association with the administration of vaccines and other biological products. The Center for Biologics Evaluation and Research (CBER) is interested in all unexpected clinical responses to a biological product, as well as any expected responses of unusual frequency or severity. In some cases, a reaction or illness could occur because the product may:

- Vary from declared potency.
- Have been contaminated during manufacturing, shipment, or after shipment.
- Be mislabeled.
- Not have been given according to directions.
- Not have been stored under proper conditions.
- Have been provided to the wrong person.
- Contain substances innocuous to most people, but which the recipient is unable to tolerate (e.g., anti-Kidd, anti-Duffy), or contains substances not usually present in such a product which stimulate an adverse response in the recipient (e.g., HLA antibodies).

8.5.1.1 - Reporting

8.5.1.1.1 - Investigation/Reporting

When a biologics reaction/injury complaint is received by a CSO, they should forward the complaint to orabiobiologicsinspectionpoc@fda.hhs.gov. The Biologics POC will then forward it to the appropriate ORA Consumer Complaint Coordinator following SOP-000544.

All complaints received by the ORA BIO Biologics Inspection POC will be reviewed and upon determination of initial follow-up status entered into the ORA Consumer Complaint Initial Disposition Work Activity for that complaint.

When interviewing the complainant about a biologics complaint /injury, obtain:

- Complete description of the complaint/injury.
- Onset and duration of the reaction/injury.
- Name of product administered, include date and time of administration.
- Manufacturer and lot number of product(s), if available.

At this point, it is generally unnecessary to conduct interviews beyond the complainant, or obtain records, until a preliminary review has been conducted. It is important to rapidly communicate the basic information about the incident, implicated product, lot, license number, manufacturer, and presence of intact units to orabiobiologicsinspectionpoc@fda.hhs.gov.

Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential source information should not be referenced in the EIR. Any findings related to complaints not involving confidential sources should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR coversheet in eNSpect. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.

If a complaint related to a vaccine product involves an adverse reaction of any kind, then a Form VAERS-1 (IOM Exhibit 8-6) should be completed online by complainant or their physician. If they cannot complete the form online, the VAERS Reporting Form can be mailed to them and they can send it to the address on the form. When you send a VAERS form to a complainant, note this fact in the Remarks Section of the CMS Consumer Complaint Report.

The Vaccine Adverse Event Reporting System (VAERS) is administered under a joint FDA/CDC contract. For reporting adverse events which occur subsequent to vaccine administration, the system utilizes a fillable online form (Form FDA VAERS 2.0) or can be directly submitted at: https://vaers.hhs.gov/reportevent.html See IOM Exhibit 8-6.

8.5.1.1.2 - Professional Reporting System for Vaccine Adverse Reactions

The National Childhood Vaccine Injury Act of 1986, 42 USC 201, was passed to achieve optimal prevention of childhood infectious diseases through immunization. At the same time, it was

intended to minimize the number and severity of adverse reactions to vaccines routinely administered to children. This law requires health care providers and vaccine manufacturers to report certain adverse events which occur following the administration of specific vaccines. The vaccines and reportable events are listed in the National Childhood Vaccine Injury Act Vaccine Injury Table. The Department of Health and Human Services (DHHS) has established a Vaccine Adverse Events Reporting System (VAERS) to accept all reports of suspected adverse events after the administration of any vaccine, in all age groups, including but not limited to those in the table.

If the complaint does not involve an adverse reaction, obtain the necessary information to allow the center to make an informed decision on follow-up at the manufacturer.

If the complaint is an adverse reaction to a biologics device, drug, or HCT/P product, an FDA 3500, MedWatch Form (See IOM Exhibit 8-7) must also be completed and forwarded to the complainant for completion by their physician. If the physician will not cooperate by completing the FDA-3500, request the complainant to do it. Assist the complainant in completing the FDA 3500, if necessary. Note in the "Remarks" section of the CMS Consumer Complaints Report that the FDA 3500 was forwarded to the complainant. MedWatch forms can be found at https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting.

If the complaint does not involve an adverse reaction, obtain information necessary to permit OBPO make an informed decision on follow-up at the manufacturer. If a complainant desires further information, refer them to CBER, Office of Biostatistics and Epidemiology, Division of Epidemiology, at 301-827-3974.

If a CSO finds that there is a complaint of a fatality where blood or a blood component is implicated and that was not already reported to CBER, the CSO should notify their supervisor. The supervisor will then follow-up with OBPO management and CBER. Reporting a fatality is required of the collecting facility, in the event of a donor reaction, and by the facility which performed the compatibility tests, in the event of a transfusion reaction. An investigation of the incident shall be conducted by either Healthcare Finance Administration (HCFA) Centers for Medicare and Medicaid Services (CMS) or FDA, based on the type of facility involved, for example, transfusion service, blood bank, plasma center or hospital. OBPO CSOs may be assigned to investigate a fatality through an assignment from CBER.

CSOs should follow OBPO’s procedure as a guide for conducting the investigation. The CSO should also refer to the eNSpect assignment for additional information regarding the investigation. If the hospital, medical examiner, or other entity either refuses to provide or requires a written request in order to provide the CSO with medical history records, a death certificate, autopsy report, or other needed records, the CSO should complete and provide the firm with the Records Request Letter, that is referenced in OBPO’s procedure.

8.5.2 - Surveillance

OBPO CSOs should review OSAR Firm 360 to determine if an existing complaint exists in preparation for conducting an inspection assignment. The CSO will review all firm information in OSAR Firm 360, including reviewing all complaints and address all complaints that do not have entries under follow-up disposition and follow-up disposition dates during the inspection assignment. Complaints related to the FEI that have an initial evaluation of FDA Action Indicated, an initial disposition is entered, and no follow-up disposition is entered will automatically be listed into the inspection assignment following SOP-000544. CSO conducts the establishment inspection and investigates those issues identified in the complaint(s) and includes observations in the summary sections in the narrative of the EIR and completes the consumer complaints tab in eNSpect.

8.5.3 - Confidential Informants

In addition to this section, please refer to the general section on Confidential Sources (Section 8.1.5.7.2.3). Complaints can originate from public sources, including establishment employees at firm's we inspect, donors, donor family members, and industry. Confidential complaints can also come through CBER and through other agencies. If the complaint is from a confidential source, the complaint information is NOT documented in the EIR. Confidential Source complaint information is documented in an Investigation Memo and saved as an attachment to the EIR. Findings are considered in the initial classification of the inspection.

8.5.4 - Complaints

8.5.4.1 - BIOLOGICAL PRODUCTS

OBPO CSOs should follow the OBPO procedure on oversight of consumer complaints. If a consumer complaint coordinator receives a complaint on a biological product, they will follow SOP-000544 for proper escalation to the Biologics CMS team. If any ORA Office receives a complaint on a biological product, regardless of licensure status, the receiving office will notify OBPO at ORABIOBiologicsInspection@fda.hhs.gov. OBPO will provide direction on how to proceed, and next steps, including instructions on any CMS entries. For additional information or inquiries, send an email to the inspection POC address above or contact either of the OBPO division directors. OBPO staff receiving a complaint from external or internal sources should send the complaint to ORABIOBiologicsInspection@fda.hhs.gov. Confidential complaints received during an inspection should be captured in a memorandum as an attachment to the EIR. The confidential source information should not be referenced in the EIR.

Any findings related to complaints not involving confidential sources should be documented in the narrative to the EIR. The complaint number for all complaints should be written in the EIR coversheet in eNSpect. The consumer complaints tab in eNSpect must be completed for any assignments with complaints. Complaint follow-up assignments will be issued in eNSpect as determined by OBPO.

8.5.4.2 -Biological Samples

Do not collect samples of a suspect product without first consulting with the supervisor. An evaluation of the preliminary information on the injury/reaction by CBER (for licensed products)

and/or the home district division (for unlicensed products, plasma, and blood products) may be necessary to determine if a sample should be collected.

8.5.4.3 - BIOLOGICS INJURY/ADVERSE REACTION REPORTS

Submit biologics injury and adverse reaction narrative reports using encrypted email or mailing. If mailing, use this address:

Food and Drug Administration
White Oak Bldg71
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

NOTE: In addition, check the "Notify EO/EOMPS?" box in FACTS for all injury and adverse reaction complaints. For serious injury/illness reports, please notify the OEM/OEO immediately at 1 (866) 300-4374 and emergency.operations@fda.hhs.gov.

8.6 - Bioresearch Monitoring Investigations

8.6.1 - Illness/Injury

8.6.1.1 - Reporting

Submit drug complaints and injuries to:

MedWatch
The FDA Medical Products Reporting Program (HFD-410)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Fax Number: 1-800--322-0178

8.6.2 - Surveillance

For Cause assignments issued to OBIMO may require interviewing of subjects to verify their participation in the clinical trial. These activities would be conducted with supervisor approval. An OP13 (or OP15 for foreign) will be created in eNSpect, for the purpose of subject interviewing, with information correlating the OP12 (or OP11) For Cause assignment. An investigational memo will be uploaded as an "Attachment" as per Section 8.1.9 *General Investigation Reporting*. Additionally, the investigational memo will be included in the EIR as an "Attachment."

8.6.3 - Complaints

Complaints are received via assignment memo from the respective center. The memo will have specifics about the complaint and any special instructions. Reporting of complaints are the same as an inspection via an EIR unless otherwise instructed (see section regarding For Cause/Fact Finding/Information Gathering above). See IOM 5.14.2 – BIMO Assignments as complaint information will be included in the overarching assignment memo.

8.7 - Tobacco Investigations

8.7.1 - Investigations Coordination

Tobacco Products Samples: When collecting tobacco product samples as a result of a product complaint or adverse report investigation, see IOM 4-24, for sample collection guidance and contact CTP's Office of Compliance and Enforcement. (extract from IOM 8.4.7.6)

8.7.2 - Complaints

Anyone who encounters a problem with a tobacco product, such as a safety issue, undesired health problem, or product defect may report it online via the FDA Safety Reporting Portal (SRP) at www.safetyreporting.hhs.gov.

Potential tobacco product violations include (but are not limited to):

- Sales to minors.
- Flavored cigarette sales.
- Illegal marketing and advertising – The Tobacco Control Act gives the FDA the ability to regulate certain marketing and advertising activities by the tobacco industry, including describing tobacco products as "light," "mild," or "low" – or claiming a product is safer or less harmful without an FDA order.
- Distributing t-shirts or other promotional or novelty items with brand names of cigarette or smokeless tobacco products.
- Sponsoring events using the brand names of cigarette or smokeless tobacco products.
- Distribution of free samples of tobacco products except in limited circumstances.
- Placement of cigarette or smokeless tobacco product vending machines in prohibited areas (or providing access to self-service or direct access of tobacco products in prohibited areas).
- Sale of cigarettes in packages of less than 20.

If you see what you believe to be a violation of the Tobacco Control Act or other related regulations, you can:

- Submit online (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm)
- Call the Tobacco Call Center using CTP's toll-free number: 1.877.CTP.1373
- Send an email: CTPCompliance@FDA.hhs.gov
- Print and mail:
  Paper form (Form FDA 3779, Potential Tobacco Product Violations Report)
  (https://www.accessdata.fda.gov/scripts/ptvr/index.cfm) to:

  Potential Tobacco Products Violation Report
  Food and Drug Administration
  Center for Tobacco Products
  Office of Compliance and Enforcement
  Document Control Center
  Building 71, Room G335
  10903 New Hampshire Avenue
  Silver Spring, MD 20993

EXHIBITS

8-1 FEDERAL ANTI-TAMPERING ACT FULL LANGUAGE

Federal Anti-Tampering Act

21 U.S.C. §1365. Tampering with consumer products

(a) Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or the labeling of, or container for, any such product, or attempts to do so, shall-

(1) in the case of an attempt, be fined under this title or imprisoned not more than ten years, or both;

(2) if death of an individual results, be fined under this title or imprisoned for any term of years or for life, or both;

(3) if serious bodily injury to any individual results, be fined under this title or imprisoned not more than twenty years, or both; and

(4) in any other case, be fined under this title or imprisoned not more than ten years, or both.

(b) Whoever, with intent to cause serious injury to the business of any person, taints any consumer product or renders materially false or misleading the labeling of, or container for, a consumer product, if such consumer product affects interstate or foreign commerce, shall be fined under this title or imprisoned not more than three years, or both.

(c)(1) Whoever knowingly communicates false information that a consumer product has been tainted, if such product or the results of such communication affect interstate or foreign commerce, and if such tainting, had it occurred, would create a risk of death or bodily injury to another person, shall be fined under this title or imprisoned not more than five years, or both.

(2) As used in paragraph (1) of this subsection, the term "communicates false information" means communicates information that is false and that the communicator knows is false, under circumstances in which the information may reasonably be expected to be believed.

(d) Whoever knowingly threatens, under circumstances in which the threat may reasonably be expected to be believed, that conduct that, if it occurred, would violate subsection (a) of this section will occur, shall be fined under this title or imprisoned not more than five years, or both.

(e) Whoever is a party to a conspiracy of two or more persons to commit an offense under subsection (a) of this section, if any of the parties intentionally engages in any conduct in furtherance of such offense, shall be fined under this title or imprisoned not more than ten years, or both.

(f)(1) Whoever, without the consent of the manufacturer, retailer, or distributor, intentionally tampers with a consumer product that is sold in interstate or foreign commerce by knowingly placing or inserting any writing in the consumer product, or in the container for the consumer product, before the sale of the consumer product to any consumer shall be fined under this title, imprisoned not more than 1 year, or both.

(2) Notwithstanding the provisions of paragraph (1), if any person commits a violation of this subsection after a prior conviction under this section becomes final, such person shall be fined under this title, imprisoned for not more than 3 years, or both.

(3) In this subsection, the term "writing" means any form of representation or communication, including hand-bills, notices, or advertising, that contain letters, words, or pictorial representations.

(g) In addition to any other agency which has authority to investigate violations of this section, the Food and Drug Administration and the Department of Agriculture, respectively, have authority to investigate violations of this section involving a consumer product that is regulated by a provision of law such Administration or Department, as the case may be, administers.

(h) As used in this section-

(1) the term "consumer product" means-

(A) any "food", "drug", "device", or "cosmetic", as those terms are respectively defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321); or

(B) any article, product, or commodity which is customarily produced or distributed for consumption by individuals, or use by individuals for purposes of personal care or in the performance of services ordinarily rendered within the household, and which is designed to be consumed or expended in the course of such consumption or use;

(2) the term "labeling" has the meaning given such term in section 201(m) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(m));

(3) the term "serious bodily injury" means bodily injury which involves-

(A) a substantial risk of death;

(B) extreme physical pain;

(C) protracted and obvious disfigurement; or

(D) protracted loss or impairment of the function of a bodily member, organ, or mental faculty; and

(4) the term "bodily injury" means-

(A) a cut, abrasion, bruise, burn, or disfigurement;

(B) physical pain;

(C) illness;

(D) impairment of the function of a bodily member, organ, or mental faculty; or

(E) any other injury to the body, no matter how temporary.

8-2 LETTER TO HEALTHCARE PROVIDER FOR MEDICAL RECORDS

To access the word document, click here. Note: Link to the Letter to Healthcare Provider for Medical Records is only available to ORA users on the FDA intranet. The link is http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=OMIJZHPT3ZE7FJRCSJ&static=false&mcuid=ANONYMOUS&mcsid=FPSFER5OBBABVCT55K. Users who need a copy of the template outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the template.

Click or tap to enter a date.

[Insert name of hospital or state medical examiner & address]

Dear [Insert name of hospital or state medical examiner]:

The United States Food and Drug Administration (FDA) requests copies of available medical records for [insert patient specifics], including [medical history records, a death certificate, autopsy report and other reports] and any other related medical records. FDA is not required to request this information from you in writing but is doing so at your request.

In providing the requested information, please note that the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information; Final Rule (Privacy Rule) permits disclosure of privacy information without a written patient authorization for specific public health purposes. Specifically, the Privacy Rule permits covered entities to disclose this type of information to "a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability, including . . . the conduct of . . . public health investigations." 45 C.F.R. § 164.512(b)(1)(i). Per the Privacy Rule, "public health authority means an agency or authority of the United States . . . including the employees or agents of such public agency . . . that is responsible for public health matters as part of its official mandate." 45 C.F.R. § 164.501. FDA, as a public health agency, meets this definition. Our authority to receive information related to FDA-regulated products comes from the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act, and regulations issued under those authorities.

The Privacy Rule permits covered entities to disclose protected health information (including personal privacy information) directly to FDA for certain public health activities, including activities related to preventing or controlling disease, injury, or disability and the conduct of public health surveillance, public health investigations, and public health interventions. As part of these public health activities, access to personal privacy information, including names and contact information, is necessary to ensure timely follow-up. FDA safeguards personal privacy information pursuant to the Freedom of Information Act and the Privacy Act, 5 U.S.C. §§ 552, 552a, and our information disclosure regulations, 21 C.F.R. Parts 20 and 21, and follows internal procedures to prevent its unauthorized disclosure.

Thank you for your assistance in this regard.

Sincerely,

|

U.S. Food and Drug Administration
XXX District
Street Address
City, State ZIP

www.fda.gov

8-3 INVESTIGATION MEMO

To access the word document, click here. Note: Link to the Investigation Memo is only available to ORA users on the FDA intranet. The link is http://qmis.fda.gov:80/mc/main/index.cfm?event=showFile&ID=C7ZQFEQOANEQ5JXMLX&static=false&mcuid=ANONYMOUS&mcsid=AQZ6DL5KXFHKBPWISH. Users who need a copy of the SOP outside FDA should use the Freedom of Information Process described in Section 8.1.3 to get a copy of the SOP.

Date: (Enter Date)

To: Recipient

From: Title and Division

Subject: Special Investigation (May be changed appropriately to the assignment)

Firm Information: ABC Firm **(May be N/A if no firm involved or you may list multiple firms)**
1st Avenue
City, State, Zip Code

FEI: 12345678

Text of Investigation (Do not use Bold Text in document)

NOTE: Be sure to update the footer with Division Address

Your Electronic Signature

(Your Name, Title, Division)

U.S. Food & Drug Administration
Address of Division

www.fda.gov

8-4 TABLE OF INCIDENT COORDINATION

Incident Type	*Coordinating Body*	*Points of Contact (POCs)*
Clusters and outbreaks of 2+ human illnesses	**CFSAN / CORE** (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, CORESignalsTeam@fda.hhs.gov
Single human illness (this includes single case retrospective incidents but also individual consumer complaints)	**CFSAN / OC** (Office of Compliance)	CFSANOCSRT@fda.hhs.gov
Clusters and outbreaks of **human illness due to pet food/feed products**	**CVM** (Center for Veterinary Medicine)	David.Rotstein@fda.hhs.gov, Mark.Glover@fda.hhs.gov
Allergen issues (any and all)	**CFSAN / OC** (Office of Compliance)	Stefano.luccioli@fda.hhs.gov
Seafood toxin incidents* (All toxins; All domestic and international waters)	**CFSAN / OFS / DSS** (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	Ronald.Benner@fda.hhs.gov Jonathan.Deeds@fda.hhs.gov Karen.Swajian@fda.hhs.gov
Molluscan shellfish outbreaks (single and multiple human illnesses)	**CFSAN / OFS / DSS** (Division of Shellfish Safety and DSST, Division of Seafood Science and Technology)	Melissa.Farrell@fda.hhs.gov (goes by Lizzie; OFS / DSS) Melissa.Abbott@fda.hhs.gov (OFS / DSS) Jessica.Jones@fda.hhs.gov (OFS / DSST)
Processed shellfish outbreaks (e.g., non-molluscan shellfish (crustaceans such as lobster, crab, crab meat, crawfish, shrimp, and processed molluscan shellfish))	**CFSAN / CORE** (Coordinated Outbreak Response and Evaluation Network)	CORE Signals Team, CORESignalsTeam@fda.hhs.gov
Kratom-related / CBD / psychoactive substance incidents	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations)	FDA Emergency Operations list: emergency.operations@fda.hhs.gov
Hepatitis A positive samples (and subsequent coordination with CDC for PEP); no known associated HAV illnesses	**FDA Liaison to CDC**	FDA Liaison to CDC (Susan.Lance@fda.hhs.gov)

Infant illnesses* (*Salmonella, Cronobacter,* infant botulism with rule-out investigations for infant formula or related infant products such as gripe water or medicated foods)	**CFSAN / OC** (Office of Compliance) - Powdered Infant Formula (PIF) **CFSAN / ONFL** (Office of Nutrition and Food Labeling) **NCCC** National Consumer Complaint Coordinator	OC contact for PIF is Marjorie.Davis@fda.hhs.gov ONFL contact for infant formula are Andrea.Lotze@fda.hhs.gov and Carrie.Assar.@fda.hhs.gov NCCC in OEO is Sheila.vanTwuyver@fda.hhs.gov
Disasters (Natural and Manmade)	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations)	FDA Emergency Operations list: emergency.operations@fda.hhs.gov
Food Defense incidents (Intentional Contamination)	**OC / OO / OSEM / OEM / OEO** (Office of Emergency Operations) *And* **CFSAN / OAO** (Office of Analytics and Outreach)	CFSAN/OAO/Food Defense and Emergency Coordination Staff contact is Leeanne.jackson@fda.hhs.gov

8-5 CIFOR OUE Agent List

Agent Name	Median Incubation Period (Range)[1]	Primary Signs and Symptoms	Primary Specimen(s)	KEI[§]-Special group(s)	KEI-Geographic Considerations	KEI-Notable Exposures
BACTERIAL						
Arcobacter butzleri	32 hrs (6-83 hrs)[2]	D (persistent and watery), abdominal cramps, N, V	Stool in Cary-Blair, raw stool			
Bacillus anthracis	Usually ≤1 week (Up to 60 days)	Severe abdominal pain, N, V, fever, D (may be bloody), ascites, sepsis, meningitis	Blood, stool in Cary-Blair, raw stool		Recent travel to endemic areas, tropical or sub-temperate regions	Undercooked meat or hides of herbivores
Bacillus cereus, diarrheal toxin	10-16 hours (6-24 hours)	Abdominal cramps, D (watery), N	Stool in Cary-Blair, raw stool			Time and/or temperature-abused foods
Bacillus cereus, pre-formed toxin	30 min- 6 hours	Sudden onset of severe N, V, D	Stool in Cary Blair			Time and/or temperature-abused foods
Brucella spp.	3-4 weeks (1 week to several months)	Flu-like symptoms including fever, chills, sweating, HA, joint pain, weakness; may cause recurrent fevers and chronic joint pain/fatigue; *may cause diarrhea and bloody stools in acute phase*	Blood, serum	Animal handlers, especially farm workers and veterinarians		Ingestion of raw milk and dairy products
Campylobacter spp.	2-5 days (1-10 days)	D (may be bloody), abdominal cramps, Fever, possible N & V, Guillain-Barre Syndrome[3]	Stool in Cary Blair, raw stool			Undercooked or raw meat or poultry; raw milk/ milk-products
Clostridium botulinum, foodborne[£]	12-72 hours (6 hours-10 days)	V, D, blurred vision, diplopia, dysphagia, "bilateral" descending muscle weakness, cranial nerve palsies (e.g., blurred vision, diplopia, dysphagia)	Raw stool, vomitus, or serum (specimens collected prior to anti- toxin administration)			Improperly processed and canned foods in airtight containers/packaging
Clostridium botulinum, infantile[£]	3- 30 days	Lethargy, weakness, poor feeding, constipation, hypotonia, poor head control, poor gag reflex and sucking reflex	Raw stool, serum	Infants		Honey; home canned vegetables, fruits; corn syrup
Clostridium perfringens	8-16 hours (6-24 hours)	D (watery), abdominal cramps, N; fever is rare	Stool in Cary-Blair, raw stool			Time and / or temperature abused foods
Cronobacter sakazakii	Less than 28 days	Bacteremia, meningitis, necrotizing enterocolitis	Blood, stool in Cary- Blair, raw stool	Premature infants		Infant formula
Coxiella burnetii (Acute Q fever)	2-3 weeks (3-39 days)	Fever, HA, fatigue, malaise, cough, anorexia, N, V, D, abdominal pain, pneumonia	Blood with EDTA/ serum, tissue	Pregnant women, immunosuppressed, and patients with a pre-existing heart valve defects		Consumption of raw cow or goat milk; contact with cows or goats
Enterohemorrhagic *E. coli* (EHEC) (including Shiga-toxin producing E. coli (STEC) and Verotoxin producing E. coli (VTEC))	3-4 days (1-10 days)	D (often bloody), abdominal cramps, V, hemolytic-uremic syndrome (HUS)	Stool in Cary-Blair, raw stool	Young children		Consumption of raw milk; contact with cattle/ruminants; undercooked ground beef; leafy greens
Enterotoxigenic *E. coli* (ETEC)	24-72 hours (10 hours- 6 days)	D (profuse watery), abdominal cramps, V	Stool in Cary-Blair, raw stool		Foreign travel especially to	Contaminated water and food sources

					developing countries	
Enteroinvasive *E. coli* (EIEC)	As short as 10-18 hrs	D (watery), fever, abdominal cramps, dysentery (in rare cases)- scant stools w/ evidence of blood, mucous or leukocytes in stool	Stool in Cary-Blair, raw stool		Foreign travel especially to developing countries	
Enteropathogenic *E. coli* (EPEC)	As short as 9-12 hrs	D (watery with mucous), fever, V	Stool in Cary-Blair, raw stool	Children < 2 years of age		
Enteroaggregative *E. coli* (EAEC)	Estimated at 20-48 hrs	Chronic or acute D (watery), V	Stool in Cary-Blair, raw stool			
Diffuse-Adherence *E. coli* (DAEC)		D	Stool in Cary-Blair, raw stool	Young children		
Leptospira interrogans	5-14 days (2-30 days)	**Anicteric disease** (no liver involvement)- Abrupt onset of fever, HA, abdominal pain, N, V, severe myalgia, malaise, **conjuctival petechiae and/or hemorrhage Icteric disease** (liver involvement)- Jaundice, upper right quadrant pain, N, V, decreased urine output, edema, hemorrhage, vascular collapse, severe altered mental status (AMS)	Blood, CSF, Urine	Farmers, veterinarians, slaughterhouse, and sewer workers		Water activities (swimming, kayaking)
Listeria monocytogenes	1 day- 3 weeks (3-70 days)	**Invasive disease**- Severe HA, N, V, stiff neck, confusion, and other neurological symptoms consistent with meningitis, sepsis, bacteremia, premature birth, or stillbirth **Gastrointestinal disease**- Fever, D, myalgia	Blood, CSF, Stool in Cary-Blair	Pregnant women€, immunosuppressed¥, elderly¥		Raw milk/dairy; soft cheeses; deli or RTE meats, raw produce
Mycobacterium bovis	Undetermined	**Gastrointestinal disease**- Abdominal pain, D **Lung disease**- Fever, weight loss, night sweats, cough	Stool in Cary-Blair, sputum	Foreign born, immigrants, immunocompromised, dairy workers		Raw milk/milk products; contact with cattle, bison, elk, and deer
Salmonella spp. (non-typhi)	12-36 hours (6- 72 hours)	D (can be bloody) fever, abdominal pain, N, V	Stool in Cary-Blair, raw stool			
Salmonella Typhi/ Paratyphi	**Typhi**- 7-14 days (3-60+ days) **Paratyphi**- 1-10 days	Fever, HA, malaise, chills, myalgia, weight loss, constipation or D, bacteremia, rash, cough	Stool in Cary-Blair, raw stool		Recent travel to endemic areas; Africa, Southeast Asia	Contaminated water and food sources
Shigella spp.	24-72 hours (1-7 days)	D (stools can have blood and mucus), abdominal cramps, fever, V, tenesmus	Stool in Cary-Blair, raw stool	Young children		Usually person to person, water or raw milk
Staphylococcus aureus (preformed toxin)	1-6 hrs (30 minutes-8hrs)	Severe N, V, abdominal cramps, prostration, D, drop in blood pressure	Stool in Cary-Blair, raw stool			Foods handled with bare hands especially those without further cooking or inadequate heating/ refrigeration, time and / or temperature abused foods

Streptococcus, Group A	1-5 days	Sore throat (pharyngitis, tonsillitis), fever, malaise, rash, cellulitis	Throat swab			Milk/ raw milk, eggs, raw produce
Vibrio parahaemolyticus	12-24 hours (2-96 hours)	D (watery), N, V, abdominal cramps, HA, fever, chills; Wound infections are possible	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or undercooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp)
Vibrio vulnificus	24-72 hours (1-7 days)	V, D, abdominal pain, wound infections, bacteremia, shock	Stool in Cary-Blair, blood, wound culture	Immunocompromised, pre-existing liver conditions	Coastal, brackish waters, estuaries	Raw or under-cooked seafood (oysters, clams, squid, mackerel, tuna, sardines, crab, shrimp), contaminated water, open wounds.
Vibrio cholerae, toxigenic	24-72 hours (few hours to 5 days)	D (profuse watery), abdominal cramps, N, V, dehydration, shock	Stool in Cary-Blair, rectal swab	Immunocompromised, esp. pre-existing liver conditions	Coastal, brackish waters, estuaries esp. Pacific Northwest	Seafood, raw or under-cooked oysters, contaminated water Recent travel to endemic areas
Yersinia enterocolitica	3- 7 days (1-14 days)	Fever, abdominal pain, D, V	Stool in Cary-Blair, raw stool; blood	Children and elderly more susceptible		Undercooked pork products, raw milk
Yersinia pseudotuberculosis	3- 7 days (1-14 days)	Fever, abdominal pain, D, V, (can have scarlatiniform rash)	Stool in Cary-Blair, raw stool; blood	Males		
FUNGAL						
Cryptococcus	2 to 14 months (*C. gattii*)	D, abdominal cramps	CSF, serum	Immunocompromised	Pacific Northwest, Australia, Africa	Inhalation
PARASITIC						
Angiostrongylus cantonensis or *A. costaricensis*	1-3 weeks (1 day- 6 weeks-cantonensis); weeks-1 year (costaricensis)	Severe HA, N, V, stiff neck, and other neurological symptoms consistent with meningitis (*A. canontensis*); Abdominal pain, fever, N, V (*A. costaricensis*)	CSF, blood, serum		Texas, Pacific Basin, SE Asia (A. cantonensis); Latin America, Caribbean (*A. costaricencis*)	Raw/undercooked snails, slugs; chopped vegetables contaminated with infected snails or slugs
Cryptosporidium	7 days (1-14 days)	D (severe watery; may be recurrent), abdominal cramps, N, fever	Stool (2-3 samples collected over several days)			Recreational water, drinking water, unpasteurized milk, contact with cattle, children in daycare settings (fecal-oral transmission)
Cyclospora cayetanensis	7 days (1-14 days)	D (watery), weight loss, anorexia, abdominal cramps, N, V and fatigue; fever rare	Stool, intestinal fluid, tissue biopsy		More common in tropical and subtropical countries, but occurs in other areas due to contaminated imported produce	Fresh fruit and vegetables (e.g., berries, basil, snow peas, lettuce), contaminated water
Entamoeba histolytica	1-4 weeks (from a few days to several months or years)	Fever, chills, lower abdominal pain, D, bloody D (amoebic dysentery), liver (or other organ) abscess	Stool (2-3 samples over several days), blood if	Invasive amoebiasis more common in young adults, liver	Tropical countries with poor sanitation (South and Central	Human reservoir, fecally contaminated food or water; person-to-person less common

			disseminated	abscess more common in males, dysentery rare before age 5	America, Africa, and Asia)	
Giardia lamblia	1-3 weeks (3 days- 3 weeks)	D, abdominal cramps, greasy stools, gas	Stool (2-3 samples collected over several days)			Drinking water, recreational water, children in daycare settings (fecal-oral transmission); occasional food contamination
Toxoplasma gondii	7 days (4-23 days)	Cervical lymphadenopathy, flu-like illness; if immunocompromised, central nervous system (CNS) disease, myocarditis, or pneumonitis can occur	Serum			Raw beef
Trichinella spiralis	GI symptoms- 1-2 days; 5 days- 8 weeks for other symptoms	Muscle soreness accompanied by fever and edema of eyelids are characteristic; eosinophilia, N, V, chills, D, abdominal cramps, fatigue and weakness possible	Serum; biopsy of tissue			Consumption of raw or undercooked meat (particularly bear, pork, wild feline, fox, dog, wolf, moose, horse, seal, or walrus)
VIRAL						
Adenovirus	1-10 days	D (prolonged), N, V, HA, fever, malaise, abdominal pain; Types 40 and 41 can cause GI outbreaks	Stool in Cary-Blair, raw stool, serum, naso-pharyngeal swab,	Children		
Astrovirus	1-4 days	D (watery), N, V, fever, malaise, abdominal pain, HA, anorexia	Stool in Cary-Blair, raw stool, serum	Children and immunocompromised		Childcare facilities, long-term care facilities
Hepatitis A	28 days (15-50 days)	Jaundice, dark urine, fatigue, anorexia, N, D, fever, HA, abdominal pain, weight loss	Stool in Cary-Blair, raw stool, Serum	Men who have sex with men, injection drug users, international adoptees	Foreign travel	Water contaminated with infectious human waste; raw, under-cooked mollusks harvested from contaminated waters
Hepatitis E	26-42 days (15- 64 days)	Jaundice, dark urine, D, fever, abdominal pain, arthralgia, rash, hepatomegaly, altered consciousness	Stool in Cary-Blair, raw stool, Serum		Foreign travel, especially Asia, Middle East, Africa, and Central America; exposure to pigs	Contaminated drinking water; oysters, mussels, and other shellfish; pork, pig liver; and raw/rare deer and boar
Norovirus	12-48 hours (10- 50 hours)	N, V, D, abdominal cramps, fever (low grade), HA, myalgia, malaise	Stool in Cary-Blair, raw stool	Institutionalized populations		
Parvovirus (Human Bocavirus, HBoV 2-4)	Unknown- emerging pathogen	D, V, fever, abdominal pain, coryza, cough	Stool in Cary-Blair, raw stool, serum, CSF	Children		
Rotavirus	1-3 days	D (watery), V, fever (low grade), abdominal pain	Stool in Cary-Blair, raw stool	Children		
Saffold virus (SAFV)	Unknown-emerging pathogen	D, V, respiratory symptoms (children); if invasive, then	Stool in Cary-Blair, raw stool,	Children		

		meningitis, encephalitis, myelitis, myocarditis, enanthema, exanthema, septicemia	naso- pharyngeal swab, CSF			
Sapovirus	12-48 hours	N, V, D, abdominal pain, fever, HA, myalgia	Stool in Cary-Blair, raw stool	Infants, young children, and institutionalized populations (esp. long-term care facilities)		
OTHER						
Brainerd D agent	Unknown	D (Profuse, watery, prolonged 2-36 months)	Stool in Cary-Blair, raw stool			
Toxins						
Azaspiracid Poisoning (AZP)	12-24 hours	N, V, D, abdominal cramps	Shellfish, toxin detection		Europe	Mussels, oysters
Carchatoxin	< 1-6 hours	N, V, D, and paresthesias	Food		Madagascar	Shark, particularly the liver
Ciguatera toxin	GI symptoms- 1-6 hours (few minutes-48 hours) Neurologic symptoms- few minutes- 48 hours	N, V, D, abdominal cramps, sweating, HA, muscle aches, paresthesia of lips, tongue, face or extremities and temperature sensation reversal (hot/cold sensation flip)	Fish for purification/ extraction and mouse bioassay		Tropical areas	Predatory fish like barracuda, grouper, sea bass, snapper, mullet
Scombroid	Few minutes- 3 hours	Rash, D, flushing, sweating, HA, V, burning/tingling sensation in mouth, swelling in mouth, abdominal pain, and metallic taste	Fish, histamine testing			Fish such as tuna and mackerel; (bacterial action in) Swiss cheese
Tetrodotoxin	< 30 minutes	Paresthesia of lips, tongue, face, or extremities often following numbness; floating sensation, V, D, abdominal pain, ascending paralysis, respiratory failure	Puffer fish, toxin testing			Puffer fish consumption
Mushroom toxin (short-acting)	Few minutes- 2 hours	V, D, confusion, vision problems, salivation, diaphoresis, hallucinations	Mushrooms, toxin detection			Mushroom consumption
Mushroom toxin (long-acting)	4-24 hours	D, abdominal cramps, liver and kidney failure	Mushrooms, toxin detection			Mushroom consumption
Shellfish toxin (diarrheic)	30 minutes- 2 hours	N, V, D, abdominal pain, chills, HA, fever	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (neurotoxic)	Few minutes- 3 hours	Tingling and numbness of lips, tongue, and throat; muscle aches, dizziness and reversal of hot/cold sensation, D, V	Shellfish, toxin detection			Mussels, oysters, scallops from Gulf of Mexico, FL
Shellfish toxin (amnesic)	< 24 - 48 hours	V, D, abdominal pain and neurologic symptoms of confusion, memory loss, disorientation, seizure, or coma	Shellfish, toxin detection			Mussels, oysters, scallops

Shellfish toxin (paralytic poisoning)	30 minutes- 3 hours (15 minutes- 10 hours)	N, V, D, paresthesia of mouth and lips, weakness, dysphasia, dysphoria, respiratory paralysis	Shellfish or water, toxin detection			Scallops, mussels, clams, cockles
Chemicals						
Antimony	<1 hour (5 mins- 8 hours)	V, D, abdominal pain, metallic taste	Food or beverage			Metallic container
Arsenic	Few hours	N, V, D, pins and needles sensation, colic	Urine analysis			
Cadmium	<1 hour (5 mins- 8 hours)	N, V, D, myalgia, increased salivation, abdominal pain; often a metallic taste	Food			Seafood, oysters, clams, lobsters, grains, and peanuts
Chlorinated hydrocarbon insecticides (aldrin, chlordane, DDT, endrin, lindane, toxaphene)	30 minutes- 6 hours	N, V, paresthesia, dizziness, muscular weakness, anorexia, weight loss, confusion	Blood, urine, stools, gastric washings			Storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Copper	<1 hour (5 mins- 8 hours)	N, V (blue or green), D; often a metallic taste	Food or beverage			Metallic containers
Mercury	<1 week	N, V, D, numbness, skin rash, eye irritation, weakness of legs, spastic paralysis, impaired vision, blindness, coma	Blood, hair			Fish; grains treated with mercury containing fungicides
Monosodium glutamate (MSG)	Few minutes to 1 hour	Tingling, flushing, dizziness, HA, N, burning sensation in back of neck, forearms; feeling of tightness in chest	N/A			Foods seasoned with MSG
Nicotinic acid/Niacin	Few minutes to 1 hour	Flushing, sensation of warmth, itching, abdominal pain, puffiness of face and knees	N/A			Meats or other foods with sodium nicotinate as color preservative; high doses of dietary supplements
Nitrite poisoning	1-2 hours	N, V, cyanosis/blue skin, HA, dizziness, weakness, fatigue, loss of consciousness, chocolate-brown colored blood	Blood, food			Cured meats and spinach
Organophosphates or carbamate pesticides (Diazinon, Malathion, Parathion, TEPP; Carbaryl, Sevin®, Lannate®, Aprocarb®)	Few minutes to few hours	N, V, abdominal pain, HA, nervousness, blurred vision, twitching, convulsions	Blood, food			Spraying foods just before harvesting; storing insecticides in same areas as foods; mistaking pesticides for powdered foods
Sodium fluoride	Few minutes to 2 hours	Irritation of skin, eyes, and respiratory tract, salty or soapy taste in mouth, numbness of mouth, V, D, dilated pupils, spasms, pallor, shock, collapse	Vomitus, gastric washes, and food			Dry goods (powdered milk, flour, baking powder, cake mix), insecticides and rodenticides
Thallium	Few hours	V, D, hair loss, neurologic manifestations (paresthesia, respiratory depression, bronchospasms, cranial nerve palsies)	Urine, hair			Centers for Disease Control and Prevention. Thallium Poisoning from Eating Contaminated Cake-- Iraq, 2008. MMWR. September 19,

						2008 / 57(37);1015-1018.
Tin	Few hours	N, V, D; often a metallic taste	Food			Metallic container
Triorthocresylphosphate	10 days (5-21 days)	N, V, D, leg pain, ungainly high stepping gait, food and wrist drop	N/A			Using compound to extract foods or as cooking or salad oil
Zinc	Few hours	Stomach cramps, N, V, D, myalgias; often a metallic taste	Blood, stool, saliva, urine, and food			Metallic container

Notes:

[1] Unless otherwise noted, the median incubation period and range were obtained from the following three sources: Heymann, D.L. (Ed.)(2008). **Control of Communicable Diseases Manual** (19th ed.). Washington, DC: American Public Health Association; Centers for Disease Control and Prevention (CDC) (March 26, 2014) A-Z Index for Foodborne Illness. Retrieved from http://www.cdc.gov/foodsafety/diseases/index.html.

[2] Victoria Lappi, John R. Archer, Elizabeth Cebelinski, Fe Leano, John M. Besser, Rachel F. Klos, Carlota Medus, Kirk E. Smith, Collette Fitzgerald, and Jeffrey P. Davis. Foodborne Pathogens and Disease. March 2013, 10(3): 250-255. doi:10.1089/fpd.2012.1307.

[3] B.R. Jackson, J. Alomia Zegarra, H. Lopez-Gatell, J. Sejvar, F. Arzate, S. Waterman, A. Sanchez Nunez, B. Lopez, J. Weiss, R. Quintero Cruz, D. Y. Lopez Murrieta, R. Luna-Gierke, K. Heiman, A. R. Vieira, C. Fitzgerald, P. Kwan, M. Zarate-Bermudez, D. Talkington, V. R. Hill and B. Mahon (2014). Binational outbreak of Guillain–Barré syndrome associated with Campylobacter jejuni infection, Mexico, and USA, 2011 . Epidemiology and Infection, 142, pp 1089-1099. doi:10.1017/S0950268813001908.

§- Key epidemiological information

£- Clinical consultation and testing recommendations (including lab collection recommendations) can be obtained through consultation with CDC.

€- Pregnant women may be more likely to present with mild, flu-like symptoms.

¥- Elderly or immunocompromised may be more likely to present with sepsis or meningitis.

N- nausea, D- diarrhea, V-vomiting, HA- headache

8-6 – VAERS Form

VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

Adverse events are possible reactions or problems that occur during or after vaccination. Items **2, 3, 4, 5, 6, 17, 18 and 21** are **ESSENTIAL** and should be completed. Patient identity is kept confidential. Instructions are provided on the last two pages.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE (Use **Continuation Page** if needed)

1. Patient name: (first) _____ (last) _____
Street address: _____
City: _____ State: ____ County: _____
ZIP code: _____ Phone: ( ) _____ Email: _____
2. Date of birth: (mm/dd/yyyy) _____ 3. Sex: ☐ Male ☐ Female ☐ Unknown
4. Date and time of vaccination: (mm/dd/yyyy) _____ Time: hh:mm ☐ AM ☐ PM
5. Date and time adverse event started: (mm/dd/yyyy) _____ Time: hh:mm ☐ AM ☐ PM
6. Age at vaccination: ___ Years ___ Months 7. Today's date: (mm/dd/yyyy) _____
8. Pregnant at time of vaccination?: ☐ Yes ☐ No ☐ Unknown
(If yes, describe the event, any pregnancy complications, and estimated due date if known in item 18)

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) _____
Relation to patient: ☐ Healthcare professional/staff ☐ Patient (yourself) ☐ Parent/guardian/caregiver ☐ Other: _____
Street address: _____ ☐ Check if same as item 1
City: _____ State: ____ ZIP code: _____
Phone: ( ) _____ Email: _____
14. Best doctor/healthcare professional to contact about the adverse event: Name: _____ Phone: ( ) _____ Ext: _____

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: _____
Fax: ( ) _____
Street address: ☐ Check if same as item 13
_____
_____
City: _____
State: ____ ZIP code: _____
Phone: ( ) _____

16. Type of facility: (Check one)
☐ Doctor's office, urgent care, or hospital
☐ Pharmacy or store
☐ Workplace clinic
☐ Public health clinic
☐ Nursing home or senior living facility
☐ School or student health clinic
☐ Other: _____
☐ Unknown

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given) Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)
Use **Continuation Page** if needed

19. Medical tests and laboratory results related to the adverse event(s): (include dates)
Use **Continuation Page** if needed

20. Has the patient recovered from the adverse event(s)?: ☐ Yes ☐ No ☐ Unknown

21. Result or outcome of adverse event(s): (Check all that apply)
☐ Doctor or other healthcare professional office/clinic visit
☐ Emergency room/department or urgent care
☐ Hospitalization: Number of days (if known) _____
Hospital name: _____
City: _____ State: _____
☐ Prolongation of existing hospitalization (vaccine received during existing hospitalization)
☐ Life threatening illness (immediate risk of death from the event)
☐ Disability or permanent damage
☐ Patient died – Date of death: (mm/dd/yyyy) _____
☐ Congenital anomaly or birth defect
☐ None of the above

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4: Use **Continuation Page** if needed

Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	Dose number in series	Date Given
select			select	select	select	
select			select	select	select	

23. Has the patient ever had an adverse event following any previous vaccine?: (If yes, describe adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name)
☐ Yes _____ ☐ No ☐ Unknown

24. Patient's race: (Check all that apply) ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Native Hawaiian or Other Pacific Islander ☐ White ☐ Unknown ☐ Other: _____

25. Patient's ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

26. Immuniz. proj. report number: (Health Dept use only) _____

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at vaccination: ☐ Active duty ☐ Reserve ☐ National Guard ☐ Beneficiary ☐ Other: _____

28. Vaccinated at Military/DoD site: ☐ Yes ☐ No

FORM FDA VAERS 2.0 (03/21) SAVE

VAERS

CONTINUATION PAGE (Use only if you need more space from the front page)

17. Enter all vaccines given on the date listed in item 4 (continued):					Dose number in series
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site	
select			select	select	select
select			select	select	select
select			select	select	select
select			select	select	select

22. Any other vaccines received within one month prior to the date listed in item 4 (continued):					Dose number in series	Date Given
Vaccine (type and brand name)	Manufacturer	Lot number	Route	Body site		
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	
select			select	select	select	

Use the space below to provide any additional information (indicate item number):

FORM FDA VAERS 2.0 (03/21)

SAVE

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COMPLETING THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS) FORM

GENERAL INSTRUCTIONS

- Submit this form electronically using the Internet. For instructions, visit www.vaers.hhs.gov/uploadfile/.
- If you are unable to submit this form electronically, you may fax it to VAERS at 1-877-721-0366.
- If you need additional help submitting a report you may call the VAERS toll-free information line at 1-800-822-7967, or send an email to info@vaers.org.
- Fill out the VAERS form as completely as possible and use the **Continuation Page** if needed. Use a separate VAERS form for each individual patient.
- If you do not know exact numbers, dates, or times, please provide your best guess. You may leave these spaces blank if you are not comfortable guessing.
- You can get specific information on the vaccine and vaccine lot number by contacting the facility or clinic where the vaccine was administered.
- Please report all significant adverse events that occur after vaccination of adults and children, even if you are not sure whether the vaccine caused the adverse event.
- Healthcare professionals should refer to the VAERS Table of Reportable Events at www.vaers.hhs.gov/reportable.html for the list of adverse events that must be reported by law (42 USC 300aa-25).
- Healthcare professionals treating a patient for a suspected vaccine adverse event may need to contact the person who administered the vaccine in order to exchange information and decide how best to complete and submit the VAERS form.

SPECIFIC INSTRUCTIONS

Items 2, 3, 4, 5, 6, 17, 18 and 21 are **ESSENTIAL** and should be completed.

- **Items 4 and 5:** Provide dates and times as specifically as you can and enter as much information as possible (e.g., enter the month and year even if you don't know the day). If you do not know the exact time, but know it was in the morning ("AM") or afternoon or evening ("PM"), please provide that information.
- **Item 6:** If you fill in the form by hand, provide age in years. If a child is less than 1 year old, provide months of age. If a child is more than 1 year old but less than 2 years old, provide year and months (e.g., 1 year and 6 months). If a child is less than 1 month of age when vaccinated (e.g., a birth dose of hepatitis B vaccine) then answer 0 years and 0 months, but be sure to include the patient's date of birth (item 2) and date and time of vaccination (item 4).
- **Item 8:** If the patient who received the vaccine was pregnant at time of vaccination, select "Yes" and describe the event, any pregnancy complications, and estimated due date if known in item 18. Otherwise, select "No" or "Unknown."
- **Item 9:** List any prescriptions, over-the-counter medications, dietary supplements, herbal remedies, or other non-traditional/ alternative medicines being taken by the patient when the vaccine(s) was given.
- **Item 10:** List any allergies the patient has to medications, foods, or other products.
- **Item 11:** List any short-term or acute illnesses the patient had on the date of vaccination AND up to one month prior to this date (e.g., cold, stomach flu, ear infection, etc.). This does **NOT** include the adverse event you are reporting.
- **Item 12:** List any chronic or long-standing health conditions the patient has (e.g., asthma, diabetes, heart disease).
- **Item 13:** List the name of the person who is completing the form. Select the "Check if same as item 1" box if you are the patient or if you live at the same address as the patient. The contact information you provided in item 1 will be automatically entered for you. Otherwise, please provide new contact information.
- **Item 14:** List the doctor or other healthcare professional who is the best person to contact to discuss the clinical details of the adverse event.
- **Item 15:** Select the "Check if same as item 13" box if the person completing the form works at the facility that administered the vaccine(s). The contact information provided in item 13 will be automatically entered for you. Otherwise, provide new contact information.
- **Item 16:** Select the option that best describes the type of facility where the vaccine(s) was given.

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- **Item 17:** Include only vaccines given on the date provided in item 4. The vaccine route options include:
  - Injection/shot (intramuscular, subcutaneous, intradermal, jet injection, and unknown)
  - By mouth/oral
  - In nose/intranasal
  - Other (specify)
  - Unknown

  For body site, the options include:
  - Right arm
  - Left arm
  - Arm (side unknown)
  - Right thigh
  - Left thigh
  - Thigh (side unknown)
  - Nose
  - Mouth
  - Other (specify)
  - Unknown

  For vaccines given as a series (i.e., 2 or more doses of the same vaccine given to complete a series), list the dose number for the vaccine in the last column named "Dose number in series."
- **Item 18:** Describe the adverse event(s), treatment, and outcome(s). Include signs and symptoms, when the symptoms occurred, diagnosis, and treatment. Provide specific information if you can (e.g., if patient had a fever, provide the temperature).
- **Item 19:** List any medical tests and laboratory results related to the adverse event(s). Include abnormal findings as well as normal or negative findings.
- **Item 20:** Select "Yes" if the patient's health is the same as it was prior to the vaccination or "No" if the patient has not returned to the same state of health prior to the vaccination, and provide details in item 18. Select "Unknown" if the patient's present condition is not known.
- **Item 21:** Select the result(s) or outcome(s) for the patient. If the patient did not have any of the outcomes listed, select "None of the above." Prolongation of existing hospitalization means the patient received a vaccine during a hospital stay and an adverse event following vaccination occurred that resulted in the patient spending extra time in the hospital. Life threatening illness means you believe this adverse event could have resulted in the death of the patient.
- **Item 22:** List any other vaccines the patient received within one month prior to the vaccination date listed in item 4.
- **Item 23:** Describe the adverse event(s) following any previous vaccine(s). Include patient age at vaccination, dates of vaccination, vaccine type, and brand name.
- **Item 24:** Check all races that apply.
- **Item 25:** Check the single best answer for ethnicity.
- **Item 26:** For health department use only.
- **Items 27 and 28:** Complete only for U.S. Military or Department of Defense related reports. In addition to active duty service members, Reserve and National Guard members, beneficiaries include: retirees, their families, survivors, certain former spouses, and others who are registered in the Defense Enrollment Eligibility Reporting System (DEERS).

GENERAL INFORMATION

- VAERS (www.vaers.hhs.gov) is a national vaccine safety monitoring system that collects information about adverse events (possible reactions or problems) that occur during or after administration of vaccines licensed in the United States.
- VAERS protects patient identity and keeps patient identifying information confidential.
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits reporting of protected health information to public health authorities including the Centers for Disease Control and Prevention (CDC) and U.S. Food and Drug Administration (FDA) (45 CFR § 164.512(b)).
- VAERS accepts all reports without judging the importance of the adverse event or whether a vaccine caused the adverse event.
- Acceptance of a VAERS report by CDC and FDA does not constitute admission that the vaccine or healthcare personnel caused or contributed to the reported event.
- The National Vaccine Injury Compensation Program (VICP) is administered by the Health Resources and Services Administration (HRSA). The VICP is separate from the VAERS program and reporting an event to VAERS does not constitute filing a claim for compensation to the VICP (see www.hrsa.gov/vaccinecompensation/index.html).
- Knowingly filing a false VAERS report with the intent to mislead the Department of Health and Human Services is a violation of Federal law (18 U.S. Code § 1001) punishable by fine and imprisonment.

8-7 MedWatch Form

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration
MEDWATCH

FORM FDA 3500 (2/20)
The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Page 1 of 2

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021
See PRA statement on reverse.

FDA USE ONLY
Triage unit sequence #
FDA Rec. Date

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

A. PATIENT INFORMATION

1. Patient Identifier
In Confidence

2. Age
☐ Year(s) ☐ Month(s) ☐ Week(s) ☐ Day(s)
or Date of Birth *(e.g., 08 Feb 1925)*

3. Gender *(check one)*
☐ Female ☐ Male ☐ Intersex ☐ Transgender ☐ Prefer not to disclose

4. Weight
☐ lb ☐ kg

5. Ethnicity *(check one)*
☐ Hispanic/Latino ☐ Not Hispanic/Latino

6. Race *(check all that apply)*
☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☐ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Type of Report *(check all that apply)*
☐ Adverse Event ☐ Product Problem *(e.g., defects/malfunctions)* ☐ Product Use/ Medication Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event *(check all that apply)*
☐ Death *Date of death (dd-mmm-yyyy):*
☐ Life-threatening ☐ Disability or Permanent Damage
☐ Hospitalization (initial or prolonged) ☐ Congenital Anomaly/Birth Defects
☐ Other Serious or Important Medical Events
☐ Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event *(dd-mmm-yyyy)*

4. Date of this Report *(dd-mmm-yyyy)*

5. Describe Event, Problem or Product Use/Medication Error

(Continue on page 2)

6. Relevant Tests/Laboratory Data — Date *(dd-mmm-yyyy)*

(Continue on page 2)

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

(Continue on page 2)

C. PRODUCT AVAILABILITY

1. Product Available for Evaluation? *(Do not send product to FDA)*
☐ Yes ☐ No ☐ Returned to Manufacturer on *(dd-mmm-yyyy)*

2. Do you have a picture of the product? *(check yes if you are including a picture)* ☐ Yes

D. SUSPECT PRODUCTS

1. Name, Strength, Manufacturer/Compounder *(from product label)*. Does this report involve cosmetic, dietary supplement or food/medical food? #1 ☐ Yes #2 ☐ Yes

#1 – Name and Strength	#1 – NDC # or Unique ID
#1 – Manufacturer/Compounder	#1 – Lot #
#2 – Name and Strength	#2 – NDC # or Unique ID
#2 – Manufacturer/Compounder	#2 – Lot #

2. Dose or Amount | Frequency | Route

#1			
#2			

3. Treatment Dates/Therapy Dates *(give best estimate of length of treatment (start/stop) or duration.)*
#1 Start
#1 Stop
Is therapy still on-going? ☐ Yes ☐ No
#2 Start
#2 Stop
Is therapy still on-going? ☐ Yes ☐ No

4. Diagnosis for Use *(Indication)*
#1
#2

5. Product Type *(check all that apply)*
#1 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
#2 ☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar

6. Expiration Date *(dd-mmm-yyyy)*
#1
#2

7. Event Abated After Use Stopped or Dose Reduced?
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☐ Doesn't apply
#2 ☐ Yes ☐ No ☐ Doesn't apply

E. SUSPECT MEDICAL DEVICE

1. Brand Name

2a. Common Device Name | 2b. Procode

3. Manufacturer Name, City and State

4. Model #	Lot #	5. Operator of Device ☐ Health Professional ☐ Patient/Consumer ☐ Other
Catalog #	Expiration Date *(dd-mmm-yyyy)*	
Serial #	Unique Identifier *(UDI)* #	

6a. If Implanted, Give Date *(dd-mmm-yyyy)* | 6b. If Explanted, Give Date *(dd-mmm-yyyy)*

7a. Is this a single-use device that was reprocessed and reused on a patient? ☐ Yes ☐ No

7b. If Yes to item 7a, Enter Name and Address of Reprocessor

8. Was this device serviced by a third party servicer?
☐ Yes ☐ No ☐ Unknown

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

1. Product names and therapy dates *(Exclude treatment of event)*

(Continue on page 2)

G. REPORTER *(See confidentiality section on back)*

1. Name and Address
Last Name: First Name:
Address:
City: State/Province/Region:
ZIP/Postal Code: Country:
Phone #: Email:

2. Health Professional? ☐ Yes ☐ No

3. Occupation

4. Also Reported to:
☐ Manufacturer/ Compounder ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: ☐

FORM FDA 3500 (2/20) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.
* Please see Instructions

Reset Form

U.S. Department of Health and Human Services
Food and Drug Administration
MEDWATCH

FORM FDA 3500 (2/20) *(continued)*
The FDA Safety Information and Adverse Event Reporting Program

(CONTINUATION PAGE)
For VOLUNTARY reporting of adverse events, product problems and product use/medication errors

Page 2 of 2

B.5. **Describe Event or Problem** *(continued)*

Back to Item B.5

B.6. **Relevant Tests/Laboratory Data** *(continued)*

Date *(dd-mmm-yyyy)*	Relevant Tests/Laboratory Data	Date *(dd-mmm-yyyy)*

Additional comments

Back to Item B.6

B.7. **Other Relevant History** *(continued)*

Back to Item B.7

F.1. **Concomitant Medical Products and Therapy Dates** *(Exclude treatment of event) (continued)*

Back to Item F.1

ADVICE ABOUT VOLUNTARY REPORTING

Detailed instructions available at: https://www.fda.gov/safety/medwatch-forms-fda-safety-reporting/instructions-completing-form-fda-3500

Report adverse events, product problems or product use errors with:

- Medications (drugs or biologics)
- Medical devices (including diabetes glucose-test kit, hearing aids, breast pumps, and many more)
- Combination products (medication & medical devices)
- Blood transfusions, gene therapies, and human cells and tissue transplants (for example, tendons, bone, and corneas)
- Special nutritional products (dietary supplements, medical foods, infant formulas)
- Cosmetics (such as moisturizers, makeup, shampoos and conditioners, face and body washes, deodorants, nail care products, hair dyes and relaxers, and tattoos)
- Food (including beverages and ingredients added to foods)

Report product problems – quality, performance or safety concerns such as:

- Suspected counterfeit product
- Suspected contamination
- Questionable stability
- Defective components
- Poor packaging or labeling
- Therapeutic failures (product didn't work)

Report SERIOUS adverse events. An event is serious when the patient outcome is:

- Death
- Life-threatening
- Hospitalization (initial or prolonged)
- Disability or permanent damage
- Congenital anomaly/birth defect
- Required intervention to prevent permanent impairment or damage
- Other serious (important medical events)

Report even if:

- You're not certain the product caused the event
- You don't have all the details
- Just fill in the sections that apply to your report

How to report:

- Use section D for all products except medical devices
- Attach additional pages if needed
- Use a separate form for each patient
- Report either to FDA or the manufacturer (or both)

How to submit report:

- To report by phone, call toll-free: 1-800-FDA (332)-1088
- To fax report: 1-800-FDA(332)-0178
- To report online: www.fda.gov/medwatch/report.htm

If your report involves a serious adverse event with a device and it occurred in a facility outside a doctor's office, that facility may be legally required to report to FDA and/or the manufacturer. Please notify the person in that facility who would handle such reporting.

If your report involves an adverse event with a vaccine, go to http://vaers.hhs.gov to report or call 1-800-822-7967.

Confidentiality:

The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law. The reporter's identity, including the identity of a self-reporter, may be shared with the manufacturer unless requested otherwise.

The information in this box applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information has been estimated to average 40 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed, and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

Please DO NOT RETURN this form to the PRA Staff e-mail above.

OMB statement:

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

8-8 Potential Tobacco Product Violations Form

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Potential Tobacco Product Violations Report

Form Approved: OMB No.: 0910-0716
Expiration Date: 07/31/2020
(See page 3 for PRA Statement)

Directions:

Use this form to report potential tobacco-related violations of the Federal Food, Drug, and Cosmetic Act and associated regulations. These submissions are reviewed by FDA's Center for Tobacco Products.

WHO can report? - Any member of the public.

Tell us:

WHEN did you see the potential violation?

WHERE did the potential violation occur?

WHAT is the potential violation?

WHY report? - Information we receive from the public is often very helpful in identifying problems with marketed products and possible violations of the laws that we enforce.

To submit your report, complete the form below:

Date and State Where Violation Occurred

Date potential violation occurred *(mm/dd/yyyy)*	I do not recall the date this potential violation occurred ☐	State in which potential violation occurred

Description of Product

Type	Tobacco Brand

Potential violation type *(choose all that apply)*

- ☐ Sales to minors
- ☐ Flavored cigarette sales
- ☐ Advertising/promotion/marketing
- ☐ Vending machine/direct access to cigarette or smokeless tobacco or covered tobacco products
- ☐ Free samples
- ☐ Self-service display/direct access to cigarette or smokeless tobacco
- ☐ Sale of cigarettes in packs of less than 20
- ☐ Unsure

Type of potentially violative promotional materials *(choose all that apply)*

- ☐ Newspaper
- ☐ Magazine
- ☐ Periodicals
- ☐ Billboard
- ☐ Direct mail
- ☐ In-store advertisements
- ☐ Price signage
- ☐ Posters
- ☐ Coupons
- ☐ Internet
- ☐ Unsure

Who potentially violated? *(choose all that apply)*

- ☐ Retailer
- ☐ Manufacturer
- ☐ Importer
- ☐ Distributor
- ☐ Unsure

FORM FDA 3779 (12/17) Page 1 of 3 PSC Publishing Services (301) 443-6740 EF

Potential Tobacco Product Violations Report

Description of potential violation

Name and physical address of the potential violator, if known

Retailer, manufacturer, importer, or distributor name

Street Address

Street Address Line 2

City	State/Province/Region	Postal/Zip Code

If report is about a website, insert website address:

All reports will remain private to the extent allowed by law. For more information about FDA's internet policies, please visit: http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/default.htm

May we contact you if we need additional information?

☐ No, I want my report to be anonymous. *(Please note that if you submit this form by email, FDA will receive your email address. However, if you choose "no" FDA will not contact you.)*

☐ Yes, FDA may contact me. *(Please fill in contact information below.)*

Name

Affiliation *(such as company, school, or group)*

Street Address

Street Address Line 2

(continued on next page)

Potential Tobacco Product Violations Report

City	State/Province/Region
Postal/Zip Code	Phone Number

Email

Please email me to notify me that FDA got my complaint ☐ No ☐ Yes

In order to receive a response, please configure your email spam/junk filter to allow messages from ctpcompliance@fda.hhs.gov. In most cases, this is solved by adding our email address to your address book.

If you would rather submit your report to us in writing, along with any attachments, please do so at the the following address:

Food and Drug Administration
Center for Tobacco Products
Document Control Center
Building 71, Room G335
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

To reach us by telephone, please call 1-877-CTP-1373, and select option 3.
You may also email us at ctpcompliance@fda.hhs.gov.

Submit By Email Print Form Reset Form

An email message automatically will be produced when you click the SUBMIT BY EMAIL button. In the resulting email message, please don't forget to click the "Send" button or its equivalent when you are ready to send the email.

OMB Paperwork Reduction Act Statement

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden for this collection of information is estimated to average 0.25 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to the following address:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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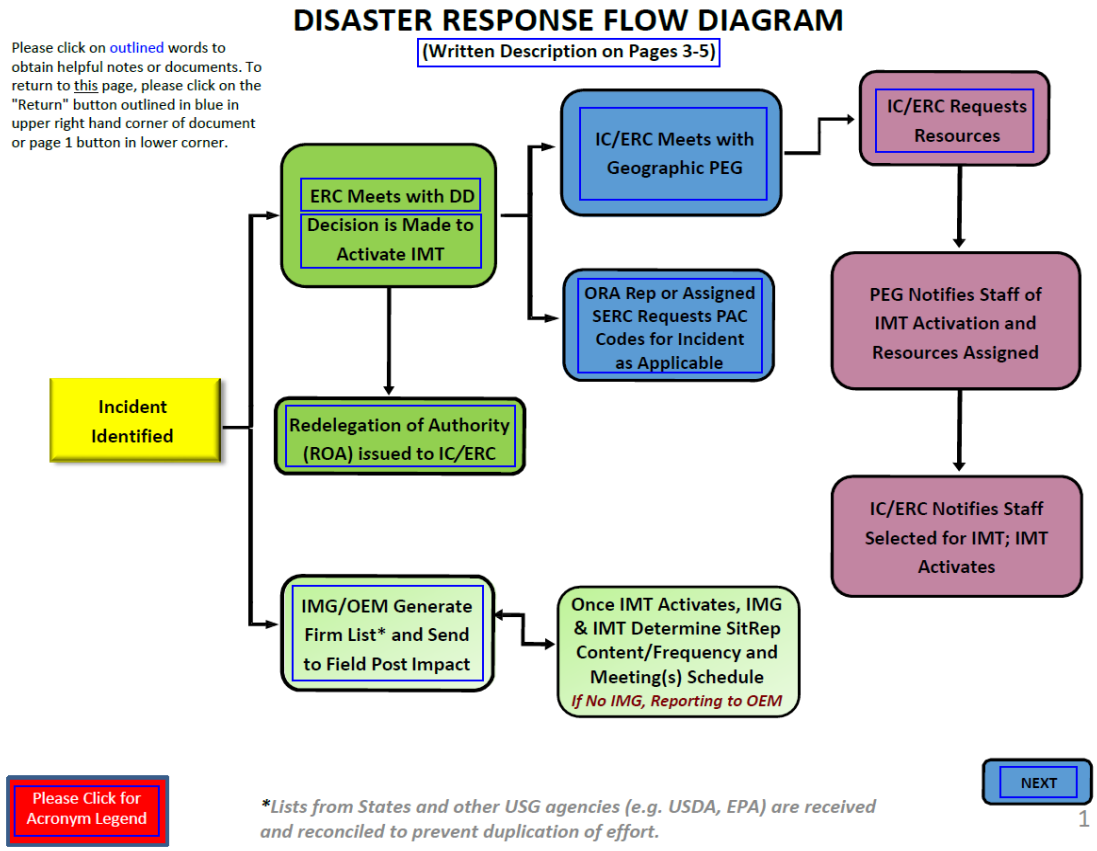
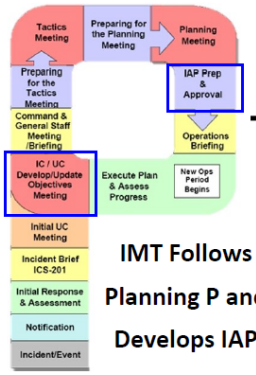
8-9 – Disaster Response Flow Diagram



DISASTER RESPONSE FLOW DIAGRAM



IMT Follows Planning P and Develops IAP

Please click on outlined words to obtain helpful notes or documents. To return to this page, please click on the"Return" button outlined in blue in upper right hand corner of document.

Operations Section Begins Telephone Assessments

Site Visits Using OP13 Conducted as Warranted *(Based upon Phone Assessment Intel)*

SitReps Issued per Agreed Upon Frequency

IMT Demobilizes Once Incident is Stabilized*

Uncontacted Firms Sent to Program(s) for Follow-up

Records Maintained per ORA Policy

After Action Review Conducted; Report Generated

Notes

- 2020 IMH
- For Expansion of IMT; Contact PEG or IMG for Additional Resources
- Reconcile Firm Lists Daily based on Work Accomplished
- SitRep Examples
- After Action Report Examples
- Additional Transition to Progam Email
- ROA Example

PAGE 1

2

* *Demobilization announced in last SitRep*

Disaster Response Flow Diagram

(Steps are Not Always Sequential)

1. Incident identified.
2. Initial notifications provided to DD/PDD or PEG based on incident.
3. ERC Meets with DD and decision is made to activate IMT. Local PDD may be in this initial meeting. *(Note: When an IMT is not activated, the ERC coordinates the disaster response with the Program Divisions.)*
   - Click link in flow diagram for discussion points for the ERC and DD/PDD meeting and AHOD or refer to page 6
   - Click link in Notes for DD/PDD meeting for Emergeny Response Resource and Funding Allocation Memo also referred to as All Hands on Deck (AHOD) memo
   - Click link in flow diagram to see IMT activation flow chart, and link in flow chart for example of PEG notification email
4. Redelegation of Authority issued to ERC/IC as applicable.
   - Click link for Redelegation of Authority (ROA) template. (Also see link of completed ROA example in Note Box on Page 2)
5. Initial communication between OEM or IMG (as applicable) and ERC/IC. *(Note: IMG is not activated for all storms; coordination is via OEM/OEO when there is no IMG.)*
   - ERC provides courtesy notification to OEM/IMG of IMT activation
   - OEM/IMG provides a map to ERC of projected area of impact prior to storm
   - OEM/IMG provides Center-vetted firm list for impacted area to PEG with copy to ERC post landfall
   - SitRep frequency and content are established with OEM/IMG. *(Note: When an IMT is not activated, ERC establishes with OEO Coordinator how updates will be provided.)*
6. DD/ERC meets with Geographic PEG to receive response priorities.
   - Click link in flow diagram for discussion points for PEG meeting or refer to page 7
   - Click link on PEG Meeting Notes page for "*Current Year" Program Priorities for Disaster Response* lists
7. Have ORA Rep or assigned SERC request PAC codes for incident if applicable. Otherwise, use General Disaster PAC Codes.
   - Click link in flow diagram for email with Natural Disaster and Emergencies PAC Codes
8. IC/ERC requests resources for IMT from PEG via Resource Request Form as warranted.
   - Click link in flow diagram for Resource Request form.

3

19. Telephone assessments and site visits are recorded as Op 13s in eNspect with the documents attached.
20. IMT records (IAP, Sitreps, emails, etc.) are stored in EON.
21. Hotwash is held prior to demobilization of IMT. A formal After Action Review is performed with IMT participants shortly after demobilization and an After Action Report generated.
    - Click link in flow diagram for Tips for Conducting an After Action Review (Also see link of After Action Report Examples in Note Box)

(Note: Click on Acronym Link on Page 1 for list of Acronyms used in document or refer to Page 8)

- Get IT assistance commitment
- Suggest initiation of *ALL HANDS ON DECK* as applicable
- Discuss number of resources and proposed length of activation
- Discuss Delegation of Authority

- Ensure PDD communicates resource commitment to supervisory level

Notes:

No completing of OEI forms. If a firm is OOB, an email or Disaster Telephone Assessment form will be sent to OEI coordinator.

Run ORADSS report prior to meeting for general picture of potential impact

RETURN

Acronym Legend

- AAR = After Action Report or After Action Review
- AHOD = All Hands on Deck
- DD = District Director
- EPA = Environmental Protection Agency
- ERC = Emergency Response Coordinator
- FSC = Finance Section Chief
- HQ = Headquarters
- IAP = Incident Action Plan
- IC = Incident Commander
- ICP = Incident Command Post
- ICS = Incident Command System
- IMG = Incident Management Group
- IMH = Incident Management Handbook
- IMT = Incident Management Team
- LSC = Logistics Section Chief
- OEM = Office of Emergency Management
- OEO = Office of Emergency Operations
- Op13 = Operation 13
- ORA = Office of Regulatory Affairs
- ORS = Office of Regulatory Science
- OSCP = Office of State Cooperative Programs
- PAC = Program Assignment Codes
- PD = Program Director
- PDD = Program Division Director
- PEG = Program Executive Group
- ROA = Redelegation of Authority
- SERC = Senior Emergency Response Coordinator
- SitRep = Situation Report
- UC = Unified Command
- USDA = United States Department of Agriculture
- USG = United States Government