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Sections included in this document

1. **Purpose**
2. **Scope**
3. **Guidelines**
4. **Procedure/Responsibilities**
5. **Background**
6. **References/Supporting Documents**
7. **Definitions/Glossary**
8. **Records**
9. **Attachments**
10. **Document and Change History**

1. Purpose

This Field Management Directive provides ORA personnel with general guidance and information related to field and headquarters responsibilities and procedures for the receipt, processing, disposition, and trending of consumer complaints.

2. Scope

This FMD applies to:

- ORA Consumer Complaint Coordinators, other field personnel receiving/processing complaints, and supervisors/branch directors overseeing complaints in each District office.
 - Office of the Commissioner (OC)/Office of Crisis Management (OCM)/Office of Emergency Operations (OEO)/National Consumer Complaint Coordinator (NCCC) and staff.
-


3. Guidelines

None

4. Responsibilities

A. District Responsibilities

District management is responsible for the oversight of consumer complaints received in their respective Districts, assuring the District has

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assigned sufficient resources to manage the receipt and processing of consumer complaints, and has assigned the complaint duties to individuals with the knowledge, skills and abilities to perform the task. The number of complaint coordinators per District should be determined by the volume of complaints received annually. In addition, Districts should have trained complaint coordinator back-ups to assist when needed.

Districts should notify the OEO NCCC of changes/updates to the District Consumer Complaint Coordinator contact information.

Districts should assign dedicated telephone lines for consumers to report complaints. Toll free telephone lines are recommended.


Districts may establish a written Standard Operating Procedure (SOP), or work instruction, for the handling of complaints including such items as logging, processing, assigning follow up activities, and trending.

District management is responsible for assuring Consumer Complaint Coordinators and others assigned to receive complaints are:

- Knowledgeable about products and problems under FDA jurisdiction;
- Knowledgeable about products and problems under the jurisdiction of other federal/state/local agencies;
- Proficient in the use of FACTS, MARCS Firm Finder, and ORADSS;
- Knowledgeable about complaint procedures: IOM Chapter 8, Investigations, FMD-119, District SOPs;
- Aware of complaint resources including the Consumer Complaint Intranet site and the Rolodex;
- Knowledgeable about provisions of the Freedom of Information Act so as not to inadvertently release personal and confidential commercial information to the public or other government agencies.

B. Consumer Complaint Coordinators or Designee Responsibilities

- Respond promptly to consumers and others reporting complaints.
- Refer consumers to appropriate agencies when products/problems are not regulated by FDA.
- Obtain complaint information corresponding to all FACTS data fields.
- Interview complainant in an attempt to obtain information about the specific product and details of its use.
- Include a thorough and clearly stated description of the problem and other relevant information in the FACTS complaint.


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- Conduct internet searches for product and problem information relative to individual complaints.
- Make an initial assessment as to whether the problem described likely resulted from production, storage, distribution, consumer handling, etc.
- Enter accurate product codes and PAC codes in FACTS.
- Enter accurate Problem Keywords/Keyword Details in FACTS.
- Assure that the correct manufacturer and the correct (active/operational) FEI is linked to the FACTS complaint.
- Consult with District management about complaints that may require immediate follow up.
- Notify OEO of complaints involving illness/injury; infant formula/baby food; product tampering; and other complaints of significance.
- Review, evaluate, and process complaints forwarded by other Districts in a timely manner. Final complaint disposition should be made after confirming the product identified is produced at the firm identified by the Receiving District and the FEI number assigned is the active/operational FEI for the firm in your District.
- Identify complaint trends as they relate to product/problems involving manufacturers located in your District.
- Follow the decision flow charts in Attachments 1-4 when determining Initial Evaluations, Initial Dispositions and Final Dispositions.
- Create appropriate FACTS Operation Assignments for complaint follow up.

C. Headquarters Responsibilities

OC/OCM/OEO is responsible for the overall management of the ORA Consumer Complaint System. The OEO NCCC and staff will:

- Serve as liaison between field complaint coordinators, the Centers, and ORA;
- Review, evaluate, and monitor follow up of complaints receiving OEO notification (via FACTS Notifications box);
- Notify Center emergency staff of significant complaints that warrant their attention and review;
- Notify CORE Signals Team regarding serious illness or injury complaints involving 2 or more unrelated individuals, associated with consumption/use of foods, dietary supplements and cosmetics;
- Notify DFFI of complaints involving serious adverse events related to products of foreign origin;
- Assist in the resolution of complaint-related issues identified by District personnel;
- Provide guidance (formal and informal) and advice to District Consumer Complaint Coordinators.


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- Conduct complaint searches as needed and/or requested
- Identify product and problem complaint trends
- Maintain the consumer complaint intranet site
- Maintain a complaint coordinator contact list
- Serve as agency point of contact for consumer complaint matters

4.1 Procedures

4.1.1 Processing Consumer Complaints

- A. Consumer complaints are entered into the FACTS Consumer Complaint database by the Consumer Complaint Coordinator in the District receiving the complaint. All consumer complaints involving FDA regulated products and problems must be entered into FACTS. Every effort should be made to accurately complete each FACTS data field. Information in these fields is important when reviewing and evaluating complaints. It is critical for use in retrieving, tracking, trending, and comparing consumer complaints. See the "FACTS Consumer Complaint Guide" link on the Consumer Complaint intranet site. (Section 6, References).
- B. Consumers or industry reporting complaints via letter, FAX, or e-mail should receive an acknowledgement from the District via phone, e-mail or letter from the CCC.
- C. In addition to recording information obtained from the complainant, the CCC receiving/processing the complaint must:
- Determine and enter the appropriate PAC Code and Product Codes into FACTS;
 - Enter Problem Keywords and Keyword Details to sufficiently identify the problem(s) reported;
 - Determine the name and location of the responsible firm (typically the manufacturing facility);
 - Identify the active/operational FEI # of the responsible firm and record the FEI # in the complaint.
- Note: Once a complaint is linked to an FEI #, it can be viewed by anyone reviewing the firm's FEI. This review is typically done in preparation for a firm inspection
- D. Complaint disposition:
- Initial Disposition is made by the District receiving the complaint.
 - Final Disposition is made by the District where the responsible firm resides (This may or may not be different from the receiving District).
 - Personnel handling consumer complaints shall follow the decision flow charts as outlined in Attachments 1-4 to determine Initial Evaluations, Initial

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Dispositions and Final Dispositions.

4.1.2 Consumer Complaints not processed through FACTS

A. Complaints received through the sources below should not be duplicated in the FACTS Consumer Complaint System, unless requested by the appropriate Center on a case-by-case basis.

1. Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report (FDA Form 1932(a)) - Center for Veterinary Medicine (CVM): Provide FDA Form 1932(a) to a consumer if they call a FDA field office to report this type of problem. (See Section 6, References).

2. Vaccine Adverse Experience Reporting System (VAERS-1) – Center for Biologics Evaluation and Research (CBER): Provide the VAERS-1 report or link to a consumer if they call a FDA field office to report this type of problem (See Section 6, References).

3. Complaints related to FDA-Regulated Clinical Trials – All Centers – refer complainants to appropriate Center as identified in the attached link.

<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ComplaintsrelatingtoClinicaltrials/default.htm>

4. Complaints involving animal biologics (vaccines, diagnostic kits and other products of biological origin) should be referred to USDA/APHIS.


http://www.aphis.usda.gov/animal_health/vet_biologics/

5. Pet Food Reports (PFR) received via the Safety Reporting Portal - (CVM)

Consumers contacting an FDA field office to report a pet food complaint should be provided the option of reporting on-line via the Safety Reporting Portal. If the consumer does not report via the Safety Reporting Portal, these complaints should be entered into the FACTS Consumer Complaint System. (See Section 6, References).

4.1.3 MedWatch FDA Form 3500

A. The MEDWATCH FDA Form 3500 can be used by healthcare professionals, patients and consumers. MedWatch collects reports of adverse reactions and quality problems, primarily with drugs, biological products (other than vaccines) and medical devices; but is also used to report problems on other FDA-regulated products (dietary supplements, cosmetics, medical foods, food additives, and

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infant formulas). Complaints received directly from consumers on these products should, in general, be reported in the FACTS Consumer Complaint System. There are situations when MedWatch is the preferred method of reporting (e.g. adverse reactions to drug products). In those instances consumers can be referred to Medwatch. (See Section 6, References).

4.1.4 Tracking and Trending Consumer Complaints

- A. Complaint data is tracked and trended via the FACTS companion system known as ORADSS. Each complaint coordinator should have a system for (1) tracking/monitoring consumer complaints and follow up; and (2) identifying trends related to products/firms within their District.
- B. The National Consumer Complaint Coordinator and staff will identify complaint trends on complaints reported to OEO via FACTS, and as requested by Centers and other FDA Headquarters Offices.

4.1.5 Complaint notification to OEO


The Office of Emergency Operations should be notified of all complaints involving serious illness (other than psychosomatic illness) or injury, hospitalization, deaths; all infant formula and baby food complaints; all complaints of suspected tampering; and all complaints involving products of foreign origin. The notification occurs once the “*Notify EO/EMOPS*” box (FACTS pg. 1) is checked and the complaint is saved. In addition, it is recommended that the OEO NCCC be notified of high priority complaints via phone or e-mail.

4.1.6 Complaints involving non-FDA regulated products or problems

- A. Field offices receiving complaints should be aware of the products and problems not regulated by FDA. Consumers should be advised how to contact the appropriate regulatory agency. If the complaint is erroneously entered into FACTS, the consumer can either be contacted by the CCC and provide information on where to report the complaint or ask the consumer for permission to forward the complaint on their behalf. NOTE: The name/address/phone number of the consumer should only be provided to another agency with the consumer’s permission. If permission is not obtained, then redact consumer identification and forward redacted copy to the appropriate agency.

4.1.7 Complaints involving foreign manufacturers

Complaints involving products made outside the U.S. should be followed up in

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the same manner as domestic product complaints. For complaints requiring no immediate follow up, FEI numbers for both the U.S. responsible firm and the foreign manufacturer should be identified, if possible, and added to FACTS. These complaints should be forwarded to the home district of the U.S. responsible firm. The OEO NCCC will forward complaints of a serious nature to ORA's Division of Foreign Field Investigations (DFFI).

4.1.8 Complaints involving Canadian manufacturers

- A. The OEO NCCC forwards significant complaints involving products made in Canada to Health Canada or the Canadian Food Inspection Agency.
-


5. Background

The ORA Consumer Complaint system is used to collect information on products in the marketplace that may be in violation of the laws and regulations administered by FDA. Complaint information is used to identify problems that have caused or have potential to cause serious adverse health consequences, as well as problems or violations of lesser significance.

Complaints are received from consumers, trade sources, healthcare professionals, or other government agencies. Complaints are received via phone, e-mail, fax, letter, or visit. NOTE: Complaints reported via letter and mailed to FDA headquarters are entered into the AIMS tracking system by ORA Office of Executive Operations. These complaints are forwarded via AIMS to the appropriate FDA District for processing.

6. References/Supporting Documents

- A. IOM, Chapter 8:
<http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515>
- B. Consumer Complaint intranet site:
<http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/ConsumerComplaints/default.htm>
- C Vaccine Adverse Event Reporting System (VAERS):
<http://vaers.hhs.gov/esub/index>
- D. FDA Form 1932(a) Veterinary Adverse Drug Reaction, Lack of Effectiveness, or Product Defect Report (For Voluntary Reporting):
<http://inside.fda.gov:9003/downloads/Administrative/Forms/FDA/UCM030608>

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E. Safety Reporting Portal:
<http://www.safetyreporting.hhs.gov>

F. Pet Food Report (PFR) Guidance:
<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm182403.htm>
<http://inside.fda.gov:9003/PolicyProcedures/SOPsbyProgram/ConsumerComplaints/ucm187305>

G. MedWatch
<http://www.fda.gov/Safety/MedWatch/default.htm>

7. Definitions

Consumer Complaint: A complaint is notification that a product in commercial distribution may be in violation of the laws or regulations administered by the FDA; and (1) may have caused illness, injury, or death; and/or (2) is alleged to have other problems (e.g. foreign objects, insects, filth, mold, abnormal containers, erroneous labeling).

Acronyms:


A. CCC	Consumer Complaint Coordinator
B. CBER	Center for Biologics Evaluation and Research
C. CVM	Center for Veterinary Medicine
D. DFFI	Division of Foreign Field Investigations
E. FACTS	Field Accomplishments and Compliance Tracking System
F. FEI	FDA Establishment Identifier
G. NCCC	National Consumer Complaint Coordinator
H. OEO	Office of Emergency Operations
I. ORADSS	ORA Reporting Analysis Decision Support System
J. PFR	Pet Food Report

8. Records

None

9. Attachments

- Attachment 1: Initial Evaluation Decision Flow Chart
- Attachment 2: Initial Disposition and Final Disposition Decision Flow Chart
- Attachment 3: Final Disposition Decision Flow Chart for Initial Disposition of "Immediate Follow Up"

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Attachment 4: Final Disposition Decision Flow Chart for Initial Disposition of “Surveillance Information For Next EI”

10. Document History

Version #	Status* (D,I, R, C)	Date	Author Name and Title	Approving Official Name and Title
* - D: Draft, I: Initial, R: Revision, C: Cancel				
1.0	I	1/12/94		
2.0	R	03/05/2012	JOAN B. TRANKLE, NATIONAL CONSUMER COMPLAINT COORDINATOR	Mark S. Roh, Regional Food & Drug Director Pacific Region

Change History

Revision 2.0 –

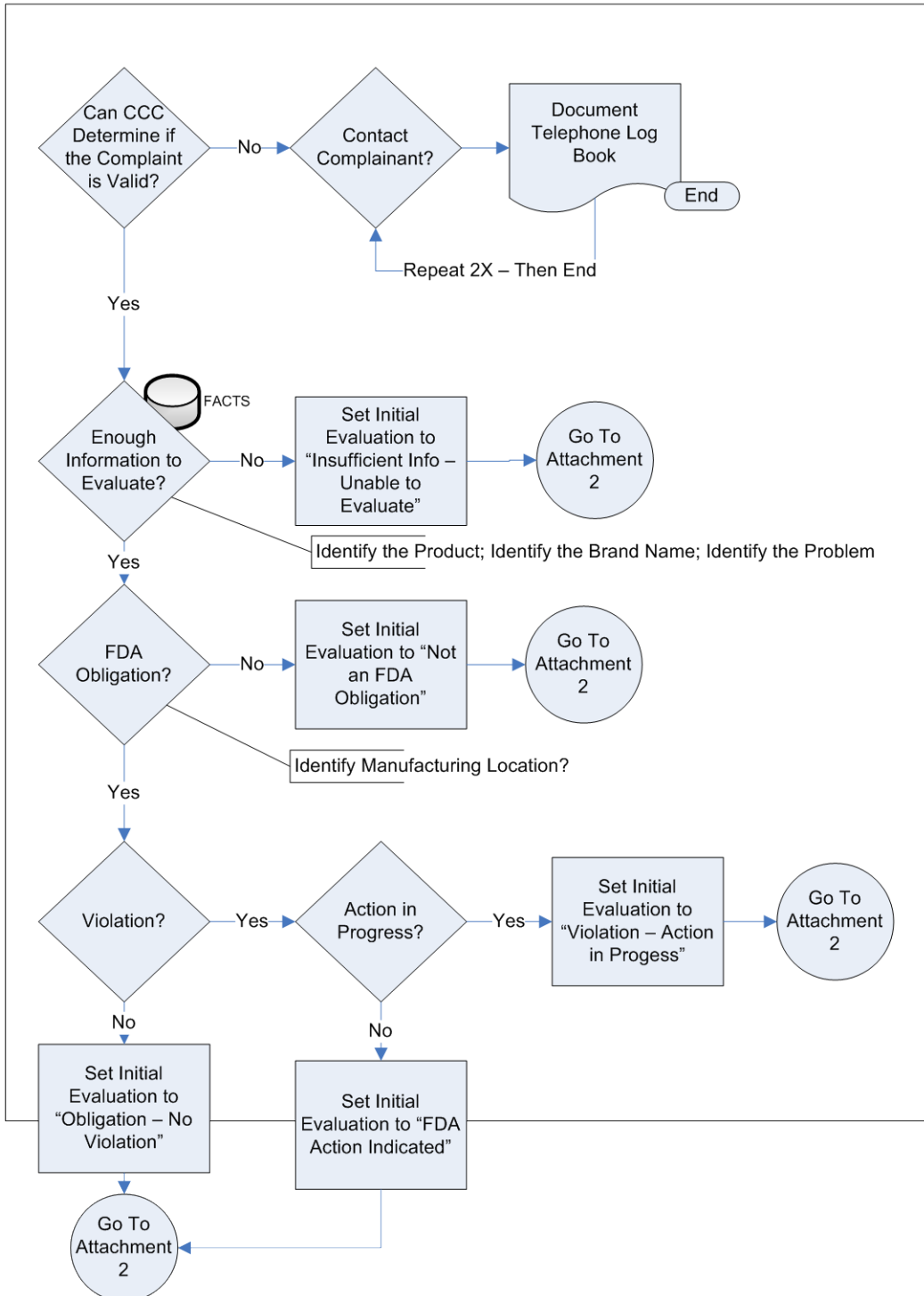
1. Updated entire FMD, added decision trees for Initial Evaluation, Initial Disposition and Final Disposition
2. Changed to current ORA FMD format



**Consumer Products Complaint System
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ATTACHMENT 1**

DATE:
3/5/2012

-  Process Step/Action
-  Decision Step
-  Documentation
-  Data Entry
-  Annotation (For Clarity)
-  On-Page Connector
-  Delay Measure
-  Database
-  Off-Page Connector





ORA-WIDE PROCEDURE

Food and Drug Administration
Office of Regulatory Affairs

ORA-QMIS
Document Number:

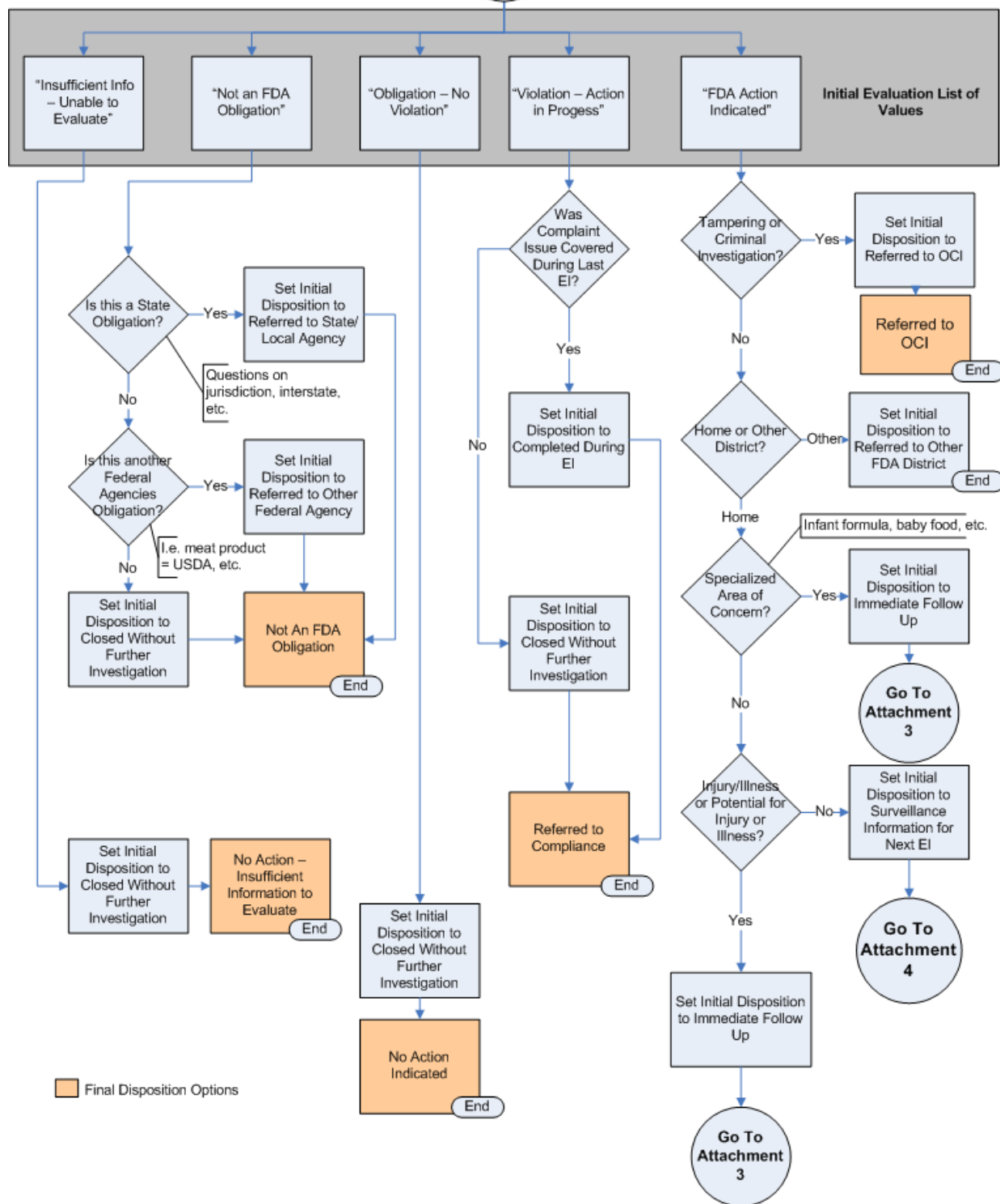
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Consumer Products Complaint System (FMD# -119) ATTACHMENT 2

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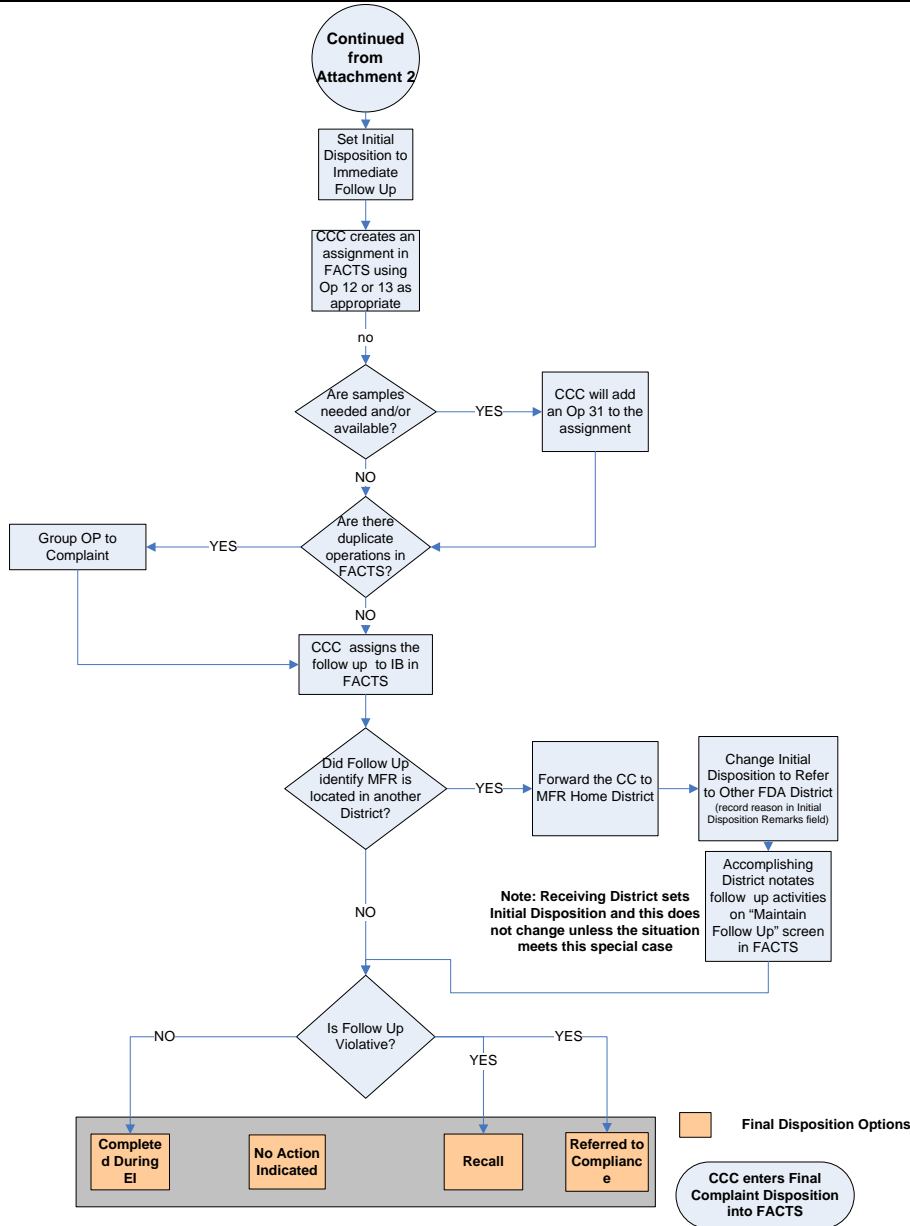
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Attachment
1





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