1.0 Purpose

The purpose of this procedure is to describe the Complaint Handling program and all the necessary steps of how complaints will be received, investigated and documented. It will ensure that complaints are processed in a uniform and timely manner and be properly linked to the CAPA, returns and recall systems. The procedure includes provisions for reporting of serious adverse events to the FDA.

2.0 Scope

This procedure will apply to all quality complaints, whether received orally, electronically or in writing by any employee.

3.0 Responsibility

Quality Unit – is responsible for overall management of the activities described in this procedure.

Customer Service – is responsible for collecting details about the complaint and forwarding the information to the Quality Unit.

All employees – are responsible for reporting the receipt of any complaints, inquiries or feedback to Customer Service.

4.0 Safety Considerations

Care shall be exercised when unloading customer returned material to the warehouse. The material may have shifted or may not be properly secured to the pallet. Always wear facility required PPE including, but not limited to, safety glasses and steel toed boots.

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure

Complaint Receipt

1. Any communication received regarding a customer complaint shall be referred directly to the Customer Service Representative (CSR) that handles their account. All other complaints, including Serious Adverse Events (SAE) should be referred to the Director of Quality; or if unavailable, to the Director of Operations.

2. The following information is required to be recorded on the *Complaint In-take Information and Initiation* form *(Q13-PR-100-F019)*:

    a) Information about complainant (and/or submitter) - name, address, phone number and email
    b) Information about the product – name, description, lot, expiry date, quantity
    c) Nature of complaint and how product was used (if applicable)
    d) Note any actions taken by complainant
    e) Specify whether a sample is available
    f) Note any reply given to complainant
    g) Name of representative completing in-take form and date

3. In the case of a customer complaint, note if any special instructions or communication restrictions need to be followed.

4. Upon completion of the *Complaint In-take Information and Initiation* form, forward form with any relevant documents (shipping, email, picture, etc.) to the Director of Quality within 24 hours of receipt of the complaint. Additionally, forward a copy of the form to the appropriate sales representative.

Complaint Evaluation

1. The Director of Quality will review the *Complaint In-take Information and Initiation* form, relevant documentation and product sample, if available, to determine whether an investigation is necessary. In either case, the Director of Quality or Designee will contact the complainant to assure them that the Quality Unit is evaluating their complaint. Contact should be made no later than seven days from receipt of the complaint. The appropriate sales representative will be notified when the complainant has been contacted.

2. The complaint will be classified into one of the following categories and assigned a number from the Complaint Log:

    a) Formal Complaint – investigation required and must be reported to management
    b) Feedback – investigation not required
    c) Inquiry – investigation not required
    d) Serious Adverse Event (SAE) – investigation required and must be reported to management and the FDA

3. An adverse event is any undesirable experience associated with the use of our product by a consumer. The event is defined as serious and should be reported to FDA when the outcome:

    - results in death
    - is life-threatening
    - requires inpatient hospitalization or causes prolongation of existing hospitalization
    - results in persistent or significant disability/incapacity
    - is a congenital anomaly/birth defect
    - requires intervention to prevent permanent impairment or damage
    - does not fit the other outcomes, but the event may jeopardize the consumer and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic brochospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization

Form FDA 3500A is a two-sided form that is to be completed for mandatory reporting of adverse events as designated in the applicable statues and FDA regulations for OTC. The form must be filed no later than **15** days after receipt of an SAE complaint. Fatal or life-threatening suspected adverse reactions are to be reported no later than seven (**7**) calendar days after learning of the event. The form and instructions may be found at:

http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/

Complaint Investigation

1. Where an investigation is not conducted, the reason that such investigation was found not to be necessary and the name of who was responsible for the decision will be documented unless the complaint was classified as feedback or an inquiry.

2. Where adequate information does exist, complaints shall be investigated. The Director of Quality will assign the investigation to the appropriate department/personnel. The complaint investigation should include but is not limited to:

    a) Review of the complaint records to evaluate if similar complaints have been received on the same lot or on previous lots manufactured
    b) The potential for other lots to be affected by the same non-conformance
    c) An attempt to obtain the complaint sample and/or picture
    d) An evaluation of returned product to include as a minimum:
        - an assessment of the integrity of the packaging
        - a determination of the length of time that the product was out on the market
        - assessment of shipping conditions
        - evidence of the storage conditions of the material
    e) A review of the manufacturing and analytical documentation associated with the complaint lot
    f) Where appropriate, analytical comparison of any returned sample(s) to the appropriate specification/requirements and any additional tests that may be warranted to investigate the complaint
    g) Where appropriate, the examination of the retain sample from the lot subject to the complaint

3. If the complaint sample as well as retained sample, both show non-conformance from the specifications/requiremints, the complaint is *confirmed*.

    When only the complaint sample is non-conforming and the non-conformance doesn't relate to any event/deviation in the manufacturing process, it will be considered a *non-confirmed* complaint. In non-confirmed cases, the complaint may be due to misuse, improper handling or inappropriate storage conditions like temperature, humidity, etc.

4. The investigation of a confirmed complaint will result in root cause analysis and a corrective action plan. The corrective actions will be implemented and documented using a *Corrective/Preventative Action Report (CAPA) (Q13-PR-100-F014a).* The Quality Unit must approve the corrective action plan and follow-up on the effectiveness of implementation.

5. If it is determined that a product recall or withdrawal is necessary, follow the steps outlined in *Recall/Withdrawal (Q12-PR-100-013).* Product *recall* is indicated when product manufactured could represent a hazard to the consumer; a hazard could range from a labeling error to a serious health hazard. A recall is conducted to protect public health and safety. A *withdrawal* is generally undertaken for quality purposes or as a precautionary measure before an official recall.

6. Product that is returned as a result of a complaint investigation or a Recall/Withdrawal must be approved, quarantined, monitored and disposed by the Quality Unit per *Returned Products (Q13-PR-100-011).* This will ensure prevention of cross-contamination and maintain traceability.

Complaint Closure

1. The time to close a complaint shall be targeted **45** days from the receipt of the complaint. The closure may be extended if additional testing or investigation is required. Extensions must be requested in writing and approved by the Quality Unit.

2. The complaint will not be officially closed until the following have been completed:

    - Quality Unit verifies the implementation of the corrective action plan.
    - Director of Quality or Designee contacts the complainant notifying them of the results of the investigation, the corrective actions implemented and availability of a copy of the *CAPA Report*.
    - Follow-up information (including costs associated with the complaint and any response provided to the originator of the complaint) is recorded on *CAPA Report.*
    - Director of Quality reviews completeness of the final *CAPA Report* (including approval signatures)

Complaint Files

1. The number of complaints, types of complaints, frequency of repeat complaints and days for closure will be tracked/trended and evaluated for CAPA effectiveness and for identifying areas of improvement. This data will be prepared by the Quality Unit and reviewed during Management Review. Further corrective actions will be taken if necessary.

2. Internal audits of the complaint handling process will be conducted annually as outlined in *Internal Quality Audits (Q12-PR-100-008).*

3. The *Complaint In-take Information and Initiation* form, *CAPA Report* and supporting documentation will be assembled in the complaint file. The file will be indentified with a unique number and filed in the cGMP library. These files will be retained for a period 4 years. Adverse event reports and records must be retained for 6 years.

7.0 Reference Documents

Complaint In-take Information and Initiation (Q12-PR-100-F019)
CAPA Management (Q12-PR-100-014)
Corrective/Preventative Report (CAPA) (Q12-PR-100-F014)
Recall/Withdrawal (Q12-PR-100-013)
Returned Products (Q13-PR-100-011)
Internal Quality Audits (Q12-PR-100-008)

8.0 Amendment Record

New Document