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**Change History**

DCO Number	Rev Level	Amended By	Effective Date	Reason/Description of Change	Approved	
					By/Date	
DCO-112	A	NA		Quality System Establishment		
DCO-142	B	JT	08/14/2016	Added Mock Recall Exercise	JT	06/14/2016



## 1. PURPOSE

This procedure provides a process for the voluntary removal of marketed product from distribution. The removal may be to ensure the correction of a violation of the laws administered by the Food and Drug Administration (FDA) or at the discretion of AMS as a response to product deficiencies.

## 2. SCOPE

This procedure applies to all marketed AMS products regulated by the FDA and at the discretion of AMS for unregulated products.

## 3. PROCEDURE

### 3.1. AMS Initiated Recall

3.1.1. AMS may decide to remove or correct a distributed product which may be in violation of the law. If the recall is because the product may be in violation, the COO, or designate, will immediately notify the appropriate local FDA office. Such removal will only be regarded as a recall if the FDA regards the product as involving a violation that is subject to legal action, e.g., seizure. In such cases AMS will be asked to provide the FDA with the following:

- Identity of the product involved
- Reason for the removal or correction and the date and circumstances under which the product deficiency was discovered.
- Evaluation of the risk associated with the deficiency.
- Total amount of product manufactured and the time span of the production.
- Total amount of product estimated to be in distribution.
- Distribution information i.e., locations etc.
- A copy of the AMS recall communication, if issued.
- Summary of proposed recall strategy.
- Contact information for person responsible for coordinating recall.

3.1.2. AMS may decide to recall product when informed by the FDA that the product violates the law, but the agency has not specifically requested a recall. The action is considered an AMS recall.

3.1.3. AMS may at its discretion voluntarily recall an unregulated product for any reason that is deemed necessary by AMS.

### 3.2. Food and Drug Administration Requested Recall

3.2.1. The FDA may request AMS to initiate a recall when the following has been determined:

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- That a distributed product presents a risk of illness or injury or gross consumer deception.
- That AMS has not initiated a recall of the product.
- That an agency action is necessary to protect consumer health and welfare.

3.2.2. The authorized representative from the FDA will notify AMS of the need to immediately initiate a product recall. The notification will specify the violation, the hazard classification of the violating product, the recall strategy, and other appropriate instructions for conducting the recall.

3.2.3. Upon receipt of request for recall, the COO will notify QA and they will take appropriate action and document the activities as required.

### 3.3. Recall Communications

3.3.1. AMS must notify each customer impacted by the product recall. The format, content, and extent of a recall communication should be commensurate with the hazard of the product being recalled. In general the recall communication should convey:

- That the product in question is subject to a recall.
- That further distribution of the product in question should cease immediately.
- Where appropriate, that the direct customer should in turn notify its customers who received the product about the recall.

### 3.4. Contents

3.4.1. A recall communication should be written in accordance with the following guidelines:

3.4.1.1. Be brief and to the point.

3.4.1.2. Identify the product, size, lot number(s), code(s), or serial numbers(s), and any other pertinent descriptive information to enable accurate identification of the product.

3.4.1.3. Explain the reason for the recall and the hazard associated with the violating product.

3.4.1.4. Detail what should be done with the recalled product in the customer's possession.

3.4.1.5. Indicate the importance for the customer to notify AMS upon receipt of the recall communication.

3.4.2. Where necessary, follow-up communications should be sent to those customers who fail to respond to the initial recall communication.



### 3.5. Recall Status Reports

3.5.1. If requested, AMS will provide recall status reports to the appropriate FDA district office.

3.5.2. The status report should include:

- Number of customers notified of the recall.
- Number of customers responding to the recall notification.
- Number of customers that did not respond.
- Number of product returned or corrected by the customer.
- Estimated time frame for completion of the recall.
- Percentage to pass a recall must not exceed 90%

3.5.3. Recall status reports will be discontinued when the recall is terminated by the FDA.

### 3.6. Mock Recall

3.6.1. A Mock recall must be conducted Annually

## 4. ATTACHMENTS

SOP-15-F1 Mock Recall Exercise

## 5. DEFINITIONS

None

## 6. RESPONSIBILITY

6.1. It is the responsibility of all personnel to notify the COO or designate that an occurrence may result in a recall of product.

6.2. Personnel familiar with the violation and product impact will assist with the investigation to determine scope of violation and necessary steps to minimize risk.

6.3. Interface with the FDA and coordination of investigation will be conducted by Executive Management or designate for FDA regulated products.

## 7. REFERENCES

None



Mock Recall Exercise  
SOP-15-F1

Date:

Start Time:

Completion Time:

Total time to complete exercise:

If the mock recall took more than 48hours to complete:

- a. Identify the reasons on the mock recall record (Deviations)
- b. Document and Implement corrective actions
- c. Repeat the mock recall

Mock Recall Exercise Participants

Name	Role	Signature

Mock Recall Exercise Scenario

Scenario Description:  Finished Product  Ingredient  Packaging Material

Name of recalled product(s): \_\_\_\_\_ Size(s): \_\_\_\_\_

Supplier/Vendor: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Reason for recall: \_\_\_\_\_

Receiving Inventory:

Date Received	Quantity Received
Total:	

Ingredient Storage Inventory:

Location	Quantity
Dry Storage	
Total:	



**Finished Product Inventory**

\*For ingredient and packaging recalls indicate how much of the ingredient was used in the finished product or how much packaging was used

Finished Product	Production Date	*Quantity used	Quantity of finished product produced	Lot Number	Location
Total:					

**Finished Product Shipped**

Finished Product	Date	Lot Number	Shipped to	Quantity Shipped
Total:				

Shipping Records matches amount confirmed to have been received by customers (Yes/No):

Effectiveness of Mock Recall Exercise (Recovery): % of product accounted for

If the mock recall was not able to account for 100% of the affected product:

- a. Identify the reasons on the mock recall record (Deviations)
- b. Document and Implement corrective actions
- c. Repeat the mock recall

Percentage of finished product reconciliation (Cases):

$$\frac{\text{____(Inventory)} + \text{____(Hold)} + \text{____(Shipped)} + \text{____ (*Employee Sales/Samples)}}{\text{_____}} \times 100 =$$

%

100 (Total finished product produced)

\*If you sell your products to employees or provide samples to potential buyers be sure to document this

Percentage of ingredient reconciliation:

$$\frac{\text{____(Inventory)} + \text{____(Hold)} + \text{____ (Quantity used in finished product)} + \text{(In-Process)}}{\text{_____}} \times$$

100 = %

(Total Quantity Received)



The following lists are confirmed to be up-to-date:

Supplier (Yes/No):

Customer (Yes/No):

Government (Yes/No):

Recall team (Yes/No):

\*Note that government authorities and customers will not be notified during a mock recall

Deviations (if any):

Corrective Actions:

What went well:

Mock Recall Exercise Completion:

Signature of Team Leader: \_\_\_\_\_

Date: \_\_\_\_\_