



1343 N. Colorado Street, Suite
111 Gilbert, AZ 85233

Product Recall Policy

Effective Date: June 14, 2021
Created Date: August 20, 2019
Date Revised: June 14, 2021
Version Number: 01

QP-005

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1. PURPOSE

- 1.1. To define the requirements for recalling a product that has been determined to be contaminated, adulterated, or misbranded and poses a threat to consumers.
- 1.2. To provide guidelines for the firm to test its ability to recall a product through mock recall exercises.

2. SCOPE

The requirements of this procedure apply to the recall of any product that has been determined to be, or is suspected of being contaminated, adulterated, or misbranded to prevent injury to consumers. This procedure also applies to any dietary supplement product produced using a raw material component, or product contact packaging component found to be contaminated, adulterated, or misbranded.

3. RESPONSIBILITIES

- 3.1. In order to protect consumers from potentially adverse effects, the manufacturer must immediately initiate a voluntary recall of any dietary supplement product that has been determined to be contaminated, adulterated, or misbranded.
- 3.2. The decision to voluntarily recall a product must be made by a responsible decision maker who has the authority to assign the recall classification to the situation in cooperation with federal and state agencies. If a product deemed contaminated, adulterated, or misbranded is not recalled, the Food and Drug Administration (FDA) may request that the company do so.
- 3.3. The Product Recall Team must be convened immediately when a Class I, II, or III situation exists.
- 3.4. All information received in the process of recalling a product must be approved by the Product Recall Coordinator.
- 3.5. All communication released regarding a product recall must be released by the Spokesperson, if this person is someone other than the Product Recall Coordinator.
- 3.6. The Shipping Manager or designee will be responsible for recording quantities, and date codes of all products shipped from the warehouse, and the Shipping Manager or a designee will be responsible for maintaining these records as hard copies or on a computer file for a period not less than one year past the expiration date of the product.



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3.7. Management must ensure that this procedure is reviewed annually.

4. THE PRODUCT RECALL TEAM

The Product Recall Team should include persons with expertise in the following areas:

- Regulatory
- Production
- Sales
- Quality Control
- Public Relations
- Legal
- Purchasing
- Nutrition

The Product Recall Team must be identified by responsibilities, and 24-hour telephone contact numbers. A suggested format for listing the members of the Product Recall Team appears as Table 1 below.

Table 1 **PRODUCT RECALL TEAM**

TITLE	RESPONSIBILITY	HOME PHONE NO.	OFFICE PHONE NO.	CELL PHONE NO.

5. RECALL CLASSIFICATIONS

Class I – This is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.

Class II – This is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product.

Class III – This is a situation where the use of the product will not cause adverse health consequences.

Class I and Class II recalls require that the FDA and customers be notified.

Class III recalls require that customers be notified.

6. REQUIRED INFORMATION

6.1. The Recall Team must collect and document the following information regarding the product to be recalled:

- Product identity (description of the product being recalled)
- Lot number
- Quantity
- Reason for the recall (nature of defect)
- Level of distribution
- The recall classification
- The FDA contact
- List of customers to be contacted
- Applicable production and distribution records

7. RECALL STRATEGY

7.1. When a product complaint is received; the Product Recall Coordinator must be notified immediately. The Product Recall Coordinator will determine the necessary actions to follow.

7.2. If a recall is deemed necessary, the Product Recall Team will be convened to collect all information, determine the recall level, and plan the recall strategy.

7.3. Using shipping records, the Product Recall Team will identify the location and quantities of all product shipped to all first-level recipients. This will include product shipped to distributors and directly to customers. If product has gone beyond first level of distribution, the Product Recall Team will work in collaboration with distributors to identify and recall product distributed to all locations.

7.4. The Product Recall Team will determine how much, if any, of the product is still held in inventory, and how much was used as samples, damaged, spilled/lost, etc.

7.5. A thorough investigation be conducted until 100% of the product is accounted for.

7.6. All activities associated with the recall must be documented using the Product Recall Plan, QP-005 Attachment A.



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8. DISPOSITION OF RECALLED PRODUCT

- 8.1. All product implicated in a recall that is returned will be identified as “Condemned for Destruction” and will be placed in an identified “Quarantine” area of the warehouse.
- 8.2. When all of the condemned product has been assembled, the product will be destroyed by an approved method at the conclusion of the investigation.

9. RECALL TERMINATION

After every reasonable effort has been made to identify the locations of the product in question, and the product has been recalled/removed from the market, the recall is considered complete when the FDA and all customers have been notified in writing.

10. MOCK RECALLS

- 10.1. The procedure described here for recalling a product must be tested on a scheduled basis to ensure its effectiveness, and the plant’s ability to recall a product. Mock recalls to the first level of distribution should be conducted semi-annually, but at minimum annually.
- 10.2. The plant should also test its ability to recall a product through the first level of distribution annually.
- 10.3. Mock recalls to the first level of distribution should be completed in less than four hours with a recovery rate of 100% of all product implicated in the trace exercise. Any deviations should be explained clearly.
- 10.4. In addition to demonstrating the ability to recall a finished product, the company’s ability to recall a finished product based on potentially defective raw materials, ingredients, or packaging materials that come in contact with the product should also be tested on a rotating basis.
- 10.5. Mock recall exercises should involve the members of the Product Recall Team who would be involved in an actual recall, as well as the alternate team members.
- 10.6. Documentation summaries should be prepared for each mock recall using the Mock Recall Form, Attachment B. This should be an accounting of product produced vs. product shipped, product on hand and product documented as damaged, lost, samples, etc. The mock recall, results, and the required time to complete the exercise should be fully documented.



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11. HISTORY OF CHANGES

Date of Change	Change Description	Justification	Supersedes Version No.	New Version No.	Approval Initials
August 20, 2019	Policy completion	Written procedure guideline	N/A	01	CC
June 14, 2021	No Changes	Annual Review	01	01	CC



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MOCK RECALL PRODUCT ACCOUNTABILITY FORM

Date of Mock Recall: _____

Starting Time: _____

End Time: _____

Product Name: _____

Product Code: _____

Lot Number: _____

Raw Material Code: _____

Quantity of Raw Material Received: _____

Packaging Material Code: _____

Quantity of Packaging Material Received: _____

Total Wt. of Finished Product Produced: _____

Total Wt. of Finished Product in Inventory: _____

Total Wt. of Finished Product as Samples,
Lost, Spilled, etc. _____

Finished Product Shipped To

Quantity

1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____

Total Weight Accounted For: _____

Percent Recovery: _____

Required Time: _____

Signature: _____

Date: _____