I. PURPOSE

A. To define the requirements for recalling a product that has been determined to be contaminated, adulterated, or misbranded and poses a threat to consumers.

B. To provide guidelines for the firm to test its ability to recall a product through mock recall exercises.

II. 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.

III. RESPONSIBILITIES

A. 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.

B. 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.

C. The Product Recall Team must be convened immediately when a Class I, II, or III situation exists.

D. All information received in the process of recalling a product must be approved by the Product Recall Coordinator.

E. All communication released regarding a product recall must be released by the Spokesperson, if this person is someone other than the Product Recall Coordinator.

F. 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.

G. Management must ensure that this procedure is reviewed annually

H. Management must notify UL (3rd party certification body) in the event of a recall or market withdrawal at UL Verification Services via email ULWarningsRecalls@ul.com without delay. This is a condition of certification.

IV. 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.

V. REQUIRED INFORMATION

A. 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 contacts
- List of customers to be contacted
- Applicable production and distribution records

VI. RECALL STRATEGY

A. 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.

B. 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.

C. 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.

D. 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.

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

F. All activities associated with the recall must be documented using the Product Recall Form, Attachment A.

VII. DISPOSITION OF RECALLED PRODUCT

A. 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.

B. When all the condemned product has been assembled, the product will be destroyed by an approved method at the conclusion of the investigation.

VIII. 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.

IX. MOCK RECALLS

A. 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.

B. The plant should also test its ability to recall a product through the first level of distribution annually.

C. 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.

D. 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 meet the product should also be tested on a rotating basis.

E. 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.

F. 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**.**

X. ATTACHMENTS

- Product Recall Form
- Mock Recall Product Accountability Form

XI. REVISION HISTORY

Revision	Changes
01	Original
02	Reformat

PRODUCT RECALL FORM

Finished Product Lot No.	Customer	Location	Recall Class	Quantity of Product to be Recalled	Initials Verifying Notification of Customer

MOCK RECALL PRODUCT ACCOUNTABILITY FORM

QA-019-F2 Rev 00

1. Date of Mock Recall: _____
2. Starting Time: _____
3. End Time: _____
4. Product Name: _____
5. Product Code: _____
6. Lot Number: _____
7. Raw Material Code: _____
8. Quantity of Raw Material Received: _____
9. Packaging Material Code: _____
10. Quantity of Packaging Material Received: _____
11. Total Wt. of Finished Product Produced: _____
12. Total Wt. of Finished Product in Inventory: _____
13. Total Wt. of Finished Product as Samples, Lost, Spilled, etc. _____

Finished Product Shipped to	Quantity
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____

I. Total Weight Accounted For: _____
II. Percent Recovery: _____
III. Required Time: _____

Signature: _____Date: _____