Standard Operating Procedure

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SECTION:

I. Purpose

1.1. This procedure describes the management of all aspects of a product recall, including correction and removal of product. It covers the specific protocol applying to mandatory and voluntary recalls.

I. Scope

2.1. This procedure applies to qualified personnel initiating and/or performing a voluntary and mandatory recall.

I. Responsibilities

3.1. Quality Unit

3.2. Receiving

3.3. Customer Service

3.4. Packaging

3.5. Production

I. Procedure

4.1. The first step involved in an integrated recall system is to establish a recall team.

A. The recall team must include a team coordinator. The Quality Manager (or in the absence of the Quality Manager, the Quality Supervisor) is appointed as the team coordinator and is responsible for identifying team members and their contact information.

B. A recall team must be assembled with qualified members of production, purchasing, marketing, quality, sales, distribution, and customer relations.

C. The recall team is responsible for investigating the cause of the recall, contacting the client and/or vendor accounts involved, contacting regulatory agencies (if necessary), and providing media communications as well as quality and technical advisory (if necessary).

4.2. In the event of a complaint preceding a recall, a complaint file must be established to record and gather all details involved.

A. Upon formal receipt of a complaint, the completed complaint form (F-0041) must be submitted to the recall team coordinator to determine if a recall is necessary.

B. If no recall is needed, proceed with the complaint procedure as outlined in SOP 2012.

C. If a recall is necessary, that designated recall team member must gather all information relating to the initial complaint.

D. An investigation is then initiated, and findings recorded on the investigation form (F-0037) per SOP 2024.

i. All products associated with the material in question must be identified.

ii. All products in company control must be identified and placed in quarantine.

iii. Samples must be requested.

iv. A root cause must be determined.

E. The president of Blisterpack Pro must be notified. The president (or designee) will serve as the sole contact for external communications.

F. The local FDA District Recall Coordinator should be notified as soon as the decision to perform a recall has been made.

G. The local Recall Coordinator is Matt Dionne 303-236-3096.

4.3. Once it has been established by the recall team that a class I, II, or III recall is necessary, the following actions must be performed:

A. Tracing of Products : A designated team member will trace all raw materials, including packaging if applicable, that went into the product. All finished products must be traced via unique lot code.

B. Production Amounts: All finished product must be accounted for. A designated team member must trace the total amount and record the information for the file. The final amounts along with the tracking information will determine which clients will need to be contacted.

C. Distribution Records: A designated team member must trace all product that was distributed and record the information for the file.

D. Customer Contact: The president of Blisterpack Pro (or designee) will contact clients who are affected by the recall. Communications will remain open until a final disposition is reached.

E. Regulatory Agency Contact: The local FDA District Coordinator (Donald Bean 303-236-3044) should be notified as soon as the decision to perform a recall has been made. The president of Blisterpack Pro (or designee) will serve as the contact.

4.4. Recall Submission to FDA: Prepare the recall submission prior to contacting the FDA District Recall Coordinator to aid FDA in assisting in the recall. The following information is recommended in FDA guidance documents. Once the information has been prepared, proceed to step 4.5 (Recall Strategy).

A. Product information.

i. Product name (include brand name and generic name).

ii. Model or order number(s).

iii. Description of the product:

a. Include whether the product is a powder, capsule, tablet, etc.

b. Intended use or indications.

c. If perishable, include the expected shelf life.

d. Include the type of packaging (box, plastic, glass, etc.).

e. Include TWO COMPLETE SETS OF ALL LABELING TO THE DISTRICT COORDINATOR (Product labeling including private labels, individual packaging label, case label, package inserters, directions for use, and promotional material if applicable).

B. Product Codes

I. Lot/unit numbers.

ii. Expiration dates.

iii. UPC codes

C. Recalling firm information

i. Firm name, address, city, state, zip code.

ii. Identify the firm type (manufacturer, repacked, etc.).

iii. Contacts for the firm: Name/title/phone/fax/email address for RECALL contact, most responsible individual at the recalling firm, and a public contact.

iv. Manufacturer: Firm name, address, city, state, zip code and FDA registration number.

v. Firm responsible for the violation/problem: Firm name, address, city, state, zip code.

D. Reason for Recall

i. Explain in detail how the product is defective.

ii. Explain how the defect affects the performance and safety of the product.

iii. If the recall is due to the presence of a foreign object, describe the size, composition, hardness, and sharpness.

iv. If the recall is due to the presence of a contaminant, explain the level of the contaminant in the product. Provide labeling, a list of ingredients, and the Material Safety Sheet.

v. If the recall is due to the failure of the product meeting specifications, provide the specifications and report all test results. Provide copies of any sample analysis.

vi. If the recall is due to an ingredient/label issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).

vii. Explain how the problem occurred as well as the date(s).

viii. Explain how the problem was discovered as well as the date discovered.

ix. Explain if the problem affects all units subject to recall or just a portion of the units subject to recall.

x. Explain why this problem affects only those products subject to recall.

xi. Provide detailed information on complaints associated with the problem. (Include date of complaint, description including injury/illness, and lot numbers).

E. Health Hazard Assessment

i. If applicable, provide an assessment of the health risk associated with the deficiency.

F. Volume of Recalled Product: Provide the following information.

i. Total quantity produced.

ii. Date(s) produced.

iii. Quantity distributed.

iv. Date(s) distributed.

v. Quantity on HOLD by recalling firm and its distribution centers.

vi. Indicate how the product is being quarantined.

vii. Estimate the amount remaining in the marketplace.

viii. Provide the status/disposition of marketed products (if known).

G. Distribution Pattern

i. Provide the number of account type (consumers, manufacturers, wholesalers, etc.).

ii. Provide the geographic areas of distribution.

iii. Provide a consignee list (include names/addresses/city/state/zip code/phone number. Indicate what the list represents).

iv. Indicate if the product was sold under government contract. If yes, provide the contract number, contract date, and implementation date.

v. Indicate if the product was sold to any federal, state, or local agency involved in the school lunch program. If yes, list the consignees and quantity sale, and ship date.

vi. Notify the "ship to" and "bill to" customers of the recall so they can retrieve product and initiate a sub-recall if needed.

4.5. Recall Strategy

A. Indicate whether the recall is voluntary or mandatory.

B. Indicate the recall level if applicable. (Class I,II, or III).

C. Indicate the level in the distribution chain to which the recall is extending (wholesale, retail, etc.).

D. Indicate the method of notification (written, phone, fax, email). A written notification must be included. Provide information on how written notification was sent (i.e., overnight, certified mail, fax). Refer to step 4.7 for guidance.

E. If the initial notification is via phone, provide a copy of the phone script to FDA.

F. Report instructions on what to do with the recalled product.

G. If a product is to be returned, include instructions.

i. In the event that a recalled product is returned, follow SOP 2030 (Returned Goods), and fill out the accompanying form F-0005.

H. Explain if the recall creates a market shortage that will impact customers.

I. Determine a course of action for out of business distributors.

J. Provide a method for destruction of recalled product, if applicable. Follow SOP 1015 and use the accompanying form F-0046 for proper product destruction.

i. If the recalled product is to be destroyed by the client, the client must submit a final disposition based on the findings of the recall team. Proof of destruction is required.

ii. Contact the FDA District Coordinator prior to destruction. FDA may choose to act as a witness of destruction.

K. If the product is to be reprocessed, explain the course of action to the FDA District Recall Coordinator prior to implementation. All actions must be conducted under current GMPs.

4.6. Public Notification

A. In the event that product may pose a significant health risk and has been distributed to customers, a press release may be necessary.

B. Consult with the local FDA District Recall Coordinator prior to issuing a press release,

C. For recalls that FDA believes a press release is warranted, the agency will issue a press release if there has not been one issued already or if the press release is inadequate.

4.7. Written Recall Notification Letters: Written notification to parties affected by the recall is required. A designated team member(s) will provide the following:

A. Letters should be flagged with the phrase "URGENT: Dietary Supplement Recall/Correction." This statement should be written on the envelope as well.

B. Include product identification information in the letter. Include an accurate and complete description of the product and any identifying codes. If applicable, enclose a copy of the product label.

C. Identify the problem and any health risks associated with it.

D. The written notification must clearly identify the depth to which the recall is to be extended. For example, if the recall is to the retail level state "The recall is to the retail level."

E. If the product is distributed further than the immediate customer, include instructions for performing a sub-recall. If the immediate customer has distributed further, they should notify their customers. Provide all information that may assist them in identifying distribution of the product.

F. Provide recall instructions in the notification letter. Examples: Remove product from sale, cease distribution, return product.

G. Include a return/response form. It should include clear instructions and allow for the client to indicate that they followed the instructions.

4.8. Once the notification has been sent, it is important to check the effectiveness of the recall. This step is called the Evaluation of the Recall. The purpose is to verify the notification letter was received by the appropriate clients and that the clients understand the letter and followed the instructions. This step also verifies that recall reached the appropriate level of distribution. If the letter was not received or understood, follow up action is required to clarify the situation. The recall team will decide the course of action. FDA may also provide assistance.

4.9. Recall Status Reports: After initiating a recall, a report will be required by the local District Coordinator on a schedule set by that coordinator. It should include the following:

A. Dates of customer notification.

B. Number of customers notified.

C. Number of customers responding.

D. Quantity of recalled product returned and/or accounted for.

E. Details of recall effectiveness checks.

F. Include an explanation of the root cause of the recall.

G. Include a corrective action plan to prevent a similar problem from occurring in the future.

H. Evaluate the recall for termination when all possible responses have been received and it has been determined that all recalled product has been recovered, reconditioned, corrected, or destroyed.

I. Provide a final status report to the FDA District Recall Coordinator. All recall documentation must be filed by the Quality department or other designated department.

4.10. Mock Recall

A. A mock recall must be conducted on an annual basis to determine the effectiveness of the recall procedure.

B. A designated team member must provide a test scenario for selecting lots of raw materials and finished product for recall tracking.

C. The recall team will test the procedure forward from the raw material stage.

D. The recall team will test the procedure backward from the final product stage.

E. A mock recall report must be documented with all findings and filed by the Quality Unit or other designated department for three years.