Product Recall Plan

| Contact Info:  | Nicki Staats  
|               | Nicki.Staats@halo.com  
|               | (815) 632-6871  
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The Importance Of Preparing For A Recall

HALO Branded Solutions provides the maximum protection for our clients’ brands through our exclusive “Secure Source” Comprehensive Product Safety Protocol. Yet, there are no guarantees when it comes to product recalls.

In the rare event HALO and one of our clients are involved in a recall, we have consulted with consumer product safety experts to develop a recall plan that minimizes any negative impact of a recall for our clients. Due to the potentially significant business consequences, a plan to quickly and effectively react is necessary to protect our clients, their brand, and the people who have received the products involved.

This plan, therefore, will help us manage through the steps of a defective product analysis and how to remove unsafe products quickly and completely from the market.

In order to mitigate human and economic damage, we must all be clear about roles and responsibilities, procedures, and important regulatory information and be prepared to move promptly as soon as we become aware of an unsafe product we have sold.
Roles and Responsibilities

Recall Coordinator

Role/Authority. The recall coordinator is granted full authority to take the steps necessary to initiate and implement all recalls with the approval and support of our client and HALO’s CEO.

Responsibilities. The recall coordinator responsibilities include:

- **Collecting Data.** Organizing and collecting the documentation of all recall decisions and actions in a master recall database
- **Leading Recall Team.** Assembling the recall committee or team.
- **Assembling Resources.** Authority to involve appropriate departments and access necessary company resources to assist the process.
- **Overseeing Recall Process.** Managing the implementation of the company’s product recall, including making necessary recall decisions.
- **Communicating With Management.** Keeping management informed at every stage of the recall.
- **Being Liaison With Authorities.** Serving as the company’s primary liaison with the CPSC, FDA, or other authorities.
Recall Team

Our company’s product recall team is composed the following persons.

<table>
<thead>
<tr>
<th>Department/Group</th>
<th>Person</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senior Manager</td>
<td>Terry McGuire</td>
<td>Sr. Vice President</td>
</tr>
<tr>
<td>Recall Coordinator</td>
<td>Jackie Yount</td>
<td>Order Compliance Coordinator</td>
</tr>
<tr>
<td>Customer Service</td>
<td>Pam Gray</td>
<td>Director of Customer Service</td>
</tr>
<tr>
<td>Sales</td>
<td>Jim Stutz</td>
<td>Executive Vice President</td>
</tr>
<tr>
<td>Information Technology</td>
<td>Dawn Olds</td>
<td>Vice President of Operations</td>
</tr>
<tr>
<td>Marketing</td>
<td>Stephanie Preston</td>
<td>Director of Marketing</td>
</tr>
<tr>
<td>Finance</td>
<td>Linda Janczkowski</td>
<td>Chief Financial Officer</td>
</tr>
<tr>
<td>Vendor Relations</td>
<td>Nicki Staats</td>
<td>Supplier Compliance Administrator</td>
</tr>
</tbody>
</table>

The recall team will be assembled at the discretion of the recall coordinator.

Team Member Responsibilities

Individual recall activities should be assigned to each prior to a recall event to prevent loss of time and confusion during a recall. A detailed checklist of specific responsibilities can be found in Appendix E.

<table>
<thead>
<tr>
<th>Person/Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Terry McGuire</td>
<td>Oversight of process, messaging and data.</td>
</tr>
<tr>
<td>Jackie Yount</td>
<td>Coordination of testing and test protocol; Consumer Product Safety Commission liason.</td>
</tr>
<tr>
<td>Jim Stutz</td>
<td>Client relationship management and messaging</td>
</tr>
<tr>
<td>Stephanie Preston</td>
<td>Messaging and communication</td>
</tr>
<tr>
<td>Nicki Staats</td>
<td>Vendor compliance protocol</td>
</tr>
</tbody>
</table>
Recall Procedures

The recall procedure outlines the activates that the HALO will take to manage the recall of our product(s) which has/have been determined to be defective, unsafe, and/or subject to regulatory action.

A defect could be the result of a manufacturing or production error; or it could result from the design of, or the materials used in, the product. A defect could also occur in a product’s contents, construction, finishing, packaging, warnings, and/or instructions.

The company’s recall procedure is carried out through four steps:

1. Product Evaluation
2. Location of products
3. Notification of affected parties
4. Product Removal

Step 1: Product Evaluation

The first step in the recall process is evaluating the product called into question. The steps involved in the evaluation process are:

1. Receive the complaint – A file should be stored that contains all product defect complaints the company receives.
   Information that should be maintained in the product complaint file is:
   - Contact information for complainer
   - Reported problem with the product
   - Product identification numbers
   - Supplier information
   - Product purchase date and location
   - Illness and Injury details
2. Provide the complaint to the Recall Coordinator for initial evaluation. If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation.
3. The Recall Committee should evaluate all necessary criteria and determine whether the product should be recalled.
   Issues that should be discussed during the meeting should be as follows:
   - What is the defect that causes the product hazard?
   - What was the cause of the product defect?
   - Where are the unsafe products? How many are there?
   - Did the product fail to comply with government safety regulations? How?
   - Was the appropriate regulatory body informed about the defect?
   - Has the supplier discontinued production and shipments of affected product(s) to clients?
4. If a recall is deemed as being necessary:
o Determine the product removal strategy appropriate to the threat and location in commerce.
o Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.
o Contact the appropriate regulatory authorities.
o Alert legal counsel, insurance, etc. as appropriate.
o What is the company’s estimate of the cost of the product recall campaign?
o How will the company prepared to deploy manpower and/or fund efforts necessary to provide replacement or replacement parts for defective products?
o What steps if any are underway to upgrade the company’s quality control or risk analysis procedures to prevent a similar product recall in the future?

A flow chart of evaluation process can be found in Appendix B.

Step 2: Identify Implicated Products

HALO must ensure the identity of all products and quantities of products implicated in the recall. In addition, related products from the supplier should be evaluated to determine possible links to the defective product.

Information about the product and its distribution should be prepared and documented. The product should be identified through description, style, color, brand, UPC code, lot number, item number, and date of manufacture or import.

The distribution list should at minimum identify:
- Customer that received the recalled product(s)
- Customer addresses
- Contact names
- Contact telephone numbers
- Type of account
- Amount of product received/shipped
- Product ship date(s)
- Amount of product returned
- Amount of product consumed

Step 3: Notification to Affected Parties

Notifications during a recall must be done in a timely manner. These notifications should be delivered to the appropriate regulatory agencies, the distribution chain, and consumers when necessary.

Recall notices are typically used to notify regulatory agencies and those businesses in the distribution chain. Press releases are generally oriented to consumers, but may be used to notify any affected party.

- Regulatory Agencies - should be notified at the earliest opportunity after the decision has been made to conduct a recall. The regulatory authority should be updated throughout the recall process.
Additional regulatory information may be obtained below:
- CPSC:
  - (301) 504-7520
- FDA:
  - (301) 796-8200

- Distribution Chain – suppliers and clients must be notified by appropriate means. It is recommended that a written recall notice be provided to all consignees. A record of all account communication should be maintained.
- Consumers - should be notified by the most effective method available such as a hotline or signs. If appropriate, a press release can be used to notify consumers.

Considerations for preparing a press release include:
- The name and location of the recalling company
- The name of the product
- The number of products involved
- A description of the hazard
- The number of incidents involving the product
- Detailed description of the product, including model numbers, colors, sizes, and labeling
- A line drawing or photograph of the product
- Major retailers and where and when the product was sold
- Complete instructions for consumers on how to participate in the recall
- CPSC posts recall news releases on its website and requests companies to provide color photographs of recalled products

Step 4: Product Removal

The procedure for product removal can be divided into five components including: removal, control, and disposition of affected product, recall effectiveness, and recall termination. Recall flow chart can be found in Appendix C.

1. Removal

All reasonable efforts must be made to remove affected products from commerce.

- Products in commerce should be detained, segregated, and handled in a manner determined by HALO.
- Products that are still in HALO’s control (e.g. inventory located onsite, in transit, in off-site storage, and in offsite distribution) should be detained, and segregated.
- All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.
2. Control of Recalled Product

When HALO Branded Solutions chooses to retain recalled product, control must be regained to prevent reentry of the product into commerce.

- All affected product returned will be clearly marked, not for sale or distribution, and stored in an area that is separated from any other products.
- All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

3. Product Disposition

The final disposition of the recovered product must be determined. The final disposition must be reviewed and approved by the regulatory agency.

Options include:

- Redirection – Products may be redirected for uses other than human consumption.
- Destruction - Products determined to be unsafe for human consumption may be destroyed or denatured, and disposed by appropriate means.
- Recondition – Products may be reworked to remove the safety risk.
- All quantities, identification codes, and disposition shall be documented.

4. Recall Effectiveness

HALO Branded Solutions is responsible for determining whether the recall is effective. Recall effectiveness check verifies that all consignees have been notified and have taken the appropriate action.

Steps include:

- Verifying that all clients have received the notification.
- Verifying that clients have taken appropriate action.
- If the response from our client is less than 100%, then the recall strategy should be reassessed.
- All verifications shall be documented.

5. Termination of a Recall

Termination of the recall process may be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness, and disposition.

A termination of the recall may be requested by submitting a written request to the regulatory authorities. Guidance for the termination of a recall is provided in Appendix C.
Mock Recall

In addition to an annual verification of the recall plan, HALO Branded Solutions will conduct a mock recall annually or whenever there are significant changes to the plan or personnel. The mock recall will include the following elements:

- Selecting a product which has reached the consumer market.
- Tracing the product from the raw ingredient (e.g. source) level to the finished product in the marketplace.
- Verifying communications systems (e.g. contact information, test emails and faxes, etc.) to outside contacts.
- Modifying the recall plan to correct any problems encountered during the test.
- Records of these mock recalls will be documented and filed appropriately.
Appendix A – Assigned Responsibilities

Recall Management

*Management approval of recall*
Terry McGuire – is responsible to decide if the recall should go forward and approve of all media communication

*Management of the recall*
Terry McGuire – is responsible for the coordination of all recall activities

*Assemble the recall committee*
Terry McGuire – is responsible to gather the recall committee and explain responsibilities

Data Collection

*Product recall log*
Nicki Staats – is responsible to create and maintain a product recall log and gather all relevant data

*Identify all products to be recalled*
Nicki Staats – is responsible for identifying and locating all products that need to be recalled

*Prepare the distribution list*
Nicki Staats – is responsible for preparing the recalled product distribution list

Communication

*Notify the appropriate regulatory authority*
Nicki Staats – is responsible for notifying the CPSC or FDA

*Prepare the press release (if required)*
Stephanie Preston – is responsible for the recall press release if the decision to prepare a press release is made

- Considerations for preparing a press release include:
  - Issuance of a press release should be the highest priority and it should be issued promptly
  - If the company decides to prepare the press release, include all relevant information

*Prepare and distribute the notice of recall*
Stephanie Preston – is responsible for preparing the written notice include all recall relevant information and distribution of the notice to all accounts that received the product

- Confirm receipt of the Notice of Recall with all accounts
- Contact accounts that have not responded to the request for conformation
- Maintain records of the account communications.

Product Recall

*Detain and Segregate all Products to be Recalled which are in your Firm’s Control*
Nicki Staats – is responsible to ensure that all products to be recalled in the firm's control are not distributed (identify, detain, and segregate products on-site, in transit, off-site storage, and off-site distribution).

**Control the recalled product(s)**
Nicki Staats – is responsible to ensure that recalled products do not re-enter commerce. Responsibilities include:

- Quarantine and clearly identify recalled products
- Reconcile quantities, identification codes, and monitor recalled products
- Document the returned products.

**Decide what to do with the recalled product(s)**
Nicki Staats – is responsible for determining the action to be taken on the recalled product (destruction, reworking, and redirection). Other related responsibilities include:

- Determine if the regulatory authority requires actions such as witnessing destruction of the recalled product
- Verify that the action taken has been effective
- Document the action(s) taken.

**Evaluation**

- Verify Recall Effectiveness
  - Nicki Staats – is responsible for verifying the effectiveness of the recall. Responsibilities include:
    - Verify that distribution of recalled products has ceased.
    - Verify that all consignees at the recall depth specified by the recall strategy have received notification about the recall.
    - Verify that consignees have taken appropriate action.
    - Document all verifications.
Appendix B - Recall Evaluation Flow Chart

Consumer Complaint → Regulator Notification → Internal Discovery → Laboratory Report

Compliance Manager Complaint → Potential Hazard Exists and Volatile → Inform Management

- No Risk
  - Management believes there is no
  - Management believes there is
  - Management believes there is SIGNIFICANT risk

Complaint handled internally

Market Withdraw

Recall committee believes there is minimal risk → Assemble Recall Committee

Recall committee believes a recall is warranted

Determine level of removal

Product not in commerce → Detain/quarantine and disposition → Stock recovery

Product in commerce → Recall initiated by recall committee
Recall initiated by recall committee

Identify and locate all products subject to recall

- Product under company control
  - Detain/quarantine and disposition
  - Provide distribution list to appropriate regulatory agency
  - Prepare distribution list
  - Prepare distribution list notice of recall
  - Determine what to do with recalled products
  - Remove products from commerce
  - Verify recall effectiveness
  - Recall effective

- Product not under company control
  - Implement recall strategy
  - Prepare distribution list
  - Prepare distribution list press release
  - Request termination of recall
  - Recall not effective