[Company Name]
Recall Plan

Reviewed by: *Signature*, Title

Date: September 1, 2016

This model Recall Plan identifies information that is either required or recommended to facilitate an effective and efficient recall. While a Recall Plan is required by the *Preventive Controls for Human Food* regulation when a hazard requiring a preventive control is identified, no specific format and content is specified. This model contains questions and templates that can be used to develop an individualized Recall Plan. A Recall Plan must be developed as part of your Food Safety Plan records if you identify a hazard requiring a preventive control.

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Recall Team

[Add, combine or delete rows to accommodate your operation]

Assignment	Person	Contact Information
Senior Operations Manager Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Publicity and Public Relations Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Sales & Marketing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Scientific Advisor Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Logistics and Receiving Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Quality Assurance Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Accountant Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Attorney Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Administrative Support		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
FDA Recall Coordinator		Office: xxx-xxx-xxxx

Determining if a Recall Action Necessary

Problem reported by	Initial Action	Decisions	Actions
Regulatory Agency believe your product is causing illness	Assemble recall team and ask agency if recall is recommended	Evaluate situation; decide if, what and how much product to recall	**If no recall is needed**: Document why not and action.
News media story on problem with a type of food you produce	Assemble recall team, review internal records		**If recall is needed**: • Assign responsibilities • Gather evidence • Analyze evidence • Get word out • Monitor recall • Dispose of product • Apply for termination of recall • Assemble recall team and debrief • Prepare for legal issues
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		
Health Department believes your produce is causing illness	Assemble recall team, contact appropriate regulatory agency		

Information Templates for FDA Communication

PRODUCT INFORMATION:

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

CODES (Lot Identification Numbers):

- UPC code(s) involved: _____
- Lot number(s) involved: _____
- Lot numbers coding system: *Describe how to read your product code: -*

  _____

  _____
- Expected shelf life of product: _____

RECALLING FIRM Contacts

Provide this information to FDA for clear communication:

Manufacturer name: [Name and address]

Position	Name, Title	Contact Information
RECALL coordinator		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Most responsible individual		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxFax: xxx-xxx-xxxx email: xxxxxxxxxx
Public contact:	*May be one of the above or another individual. If possible, it is useful to name a different individual to allow the coordinator focus on retrieving product and resolving the issue*	Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx

REASON FOR THE RECALL:

Explain in detail how product is defective or violative	
Explain how the defect affects the performance and safety of the product, including an assessment of a health risk associated with the deficiency, if any.	
If the recall is due to the presence of a foreign object, describe the foreign objects' size, composition, hardness, and sharpness.	
If the recall is due to the presence of a contaminant (cleaning fluid, machine oil, paint vapors), explain level of contaminant in the product. Provide labeling, a list of ingredients and the Material Safety Data Sheet for the contaminant.	
If the recall is due to failure of the product to meet product specifications, provide the specifications and report all test results. Include copies of any sample analysis.	
If the recall is due to a label/ingredient issue, provide and identify the correct and incorrect label(s), description(s), and formulation(s).	
Explain how the problem occurred and the date(s) it occurred.	
Explain if the problem/defect affects ALL units subject to recall, or just a portion of the units in the lots subject to recall.	
Explain why this problem affects only those products/lots subject to recall.	
Provide detailed information on complaints associated with the product/problem: • Date of complaint • Description of complaint -include details of any injury or illness • Lot Number involved	

If a State agency is involved in this recall, identify Agency and contact.	

VOLUME OF RECALLED PRODUCT:

Total quantity produced	
Date(s) produced	
Quantity distributed	
Date(s) distributed	
Quantity on HOLD	
Indicate how the product is being quarantined	
Estimate amount remaining in marketplace • distributor level	
• customer level	
Provide the status/disposition of marketed product, if known, (e.g. used, used in further manufacturing, or destroyed).	

DISTRIBUTION PATTERN:

Number of DIRECT accounts (customers you sell directly to) by type

Type	Number
▪ wholesalers/distributors	
▪ repackers	
▪ manufacturers	
▪ retail	
▪ consumers (internet or catalog sales)	
▪ federal government consignees	
▪ foreign consignees (specify whether they are wholesale distributors, retailers or users)	
▪ Geographic areas of distribution, including foreign countries	

CONSIGNEE LIST

Provide this list to the local District Recall Coordinator. Include US customers, foreign customers and federal government consignees (e.g., USDA, Veterans Affairs, Department of Defense)

Commercial customers

Name	*Street Address*	*City*	*State*	*Recall contact name*	*Contact phone number*	*Recalled product **was** shipped?*	*Recalled product **was** sold?*	*Recalled product **may have** been shipped or sold*

Was product sold under Government Contract?

Yes _____ No _____

If yes, include contact name and information above AND complete information below.

Contracting Agency	*Contract Number*	*Contract date*	*Implementation date*

School Lunch Program:

If product was sold to federal, state or local agency for the school lunch program, complete table and notify "ship to" (so they can retrieve product) and "bill to" customers (so they can initiate the sub-recall).

Consignee	*Quantity*	*Sale date*	*Shipment date*

RECALL STRATEGY:

Level in the distribution chain

Level	Included		Rationale if "No"
	Yes	No	
Wholesale/distributor			
Retail			

Instructions for Consignee Notification

Write instructions on how consignees will be notified (i.e. by mail, phone, facsimile, e-mail). NOTE: It is advisable to include a written notification so customers will have a record of the recall and your instructions. Include instructions such as:

- How letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- Draft phone script, if you decide to use phone. NOTE: If initial notification is by phone, be prepared to provide a copy of the phone script to FDA.
- Draft recall notification (see example on last page) for website and instructions for posting it, if applicable. NOTE: The web is not recommended as a sole means of customer notification.
- Draft instructions for consignees on what to do with recalled product. If there is a recall, FDA will want a copy of final instructions.
- Consider what to do for out-of-business distributors.

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Product destruction/ reconditioning

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity]
[--No Other Products Affected--]

Contact
Consumer:
1-xxx-xxx-xxx

Media Contact:
xxx-xxx-xxxx

FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].

This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- **[insert lot codes]**

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.

Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT	LOT CODE	ITEM NO.
[Company Name] [insert product name(s)]	[insert product codes(s)]	[insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]

For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com