

ANNEX A

Sample Worksheet for Recall Strategy

The MAH may use the following sample worksheet as a guidance document in preparing their own Recall Strategy.

1. Company details

Company Name	
Address	
Owner	
License to Operate No	
Activity	

2. Product Information

Brand and Product Name	
FR No.	
Intended Use	
Intended Consumer	
Type of Packaging	
Batch/Lot Number	
Manufactured Date	
Expiry Date	
Label	

3. Recall Team

Name	Office	Responsibilities	Contact Information	
			Email Address	Phone Number

4. Health Hazard Evaluation Checklist

<p>Product evaluation</p> <ol style="list-style-type: none">Is there an allergen present that is not declared on the label? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details _____Is there a potential contamination that may cause harm to the consumer? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide details _____Is the product packaging compromised?

Yes No

If yes, provide details _____

Consumer Report on the Implicated Product

1. Is there any consumer complaint?

Yes No

If yes, provide details (clear copies of data) _____

2. Are there any reported adverse reactions?

Yes No

If yes, provide details _____

3. Are there reported illnesses, injuries, or death?

Yes No

If yes, provide details _____

Identifying Population at Risk

Tick the applicable population at risk

Infant Children Elderly Pregnant and lactating Women

Others provide details _____

Identifying Associated Risks with the Use of the Implicated Food Product

Potentially life-threatening (eg. Presence of heavy metals, non-declaration of peanuts in the label)

Poisoning/ medically reversible adverse health problem (eg. Stomach pains/headaches, dizziness)

Do not pose a significant health hazard

Risk Management Option

Food Safety Issue that warrants product recall

Quality Issue (e.g., Vitamin & mineral content does not meet the level as declared on The Label, not compliant with Phil. Laws and FDA issuances such as FC 2021-028, TFA, Misleading claims as stated in Item F and H of Section VII of AO 2014-0030)

If a Product Recall is Imperative, Indicate the Classification of Recall according to the result of the Health Hazard Evaluation

Class I Recall

Class II Recall

Class III Recall

*Other documents such as scientific literature, references, and laboratory results may be attached

5. Recall Instructions

Recall Instructions		
Instructions	Person(s)-in-charge	Target Date of completion
1. Instruct to stop selling implicated products by calling/emailing: Stocks meant for recall must be removed from the selling area within 24 hours upon receipt of the letter/notice.		

2. Upon pull out of products, return slip forms should be signed by consumer/authorized retailer/distributor/pharmacist/seller. Indicate dates.		
3. During actual pull out of implicated products: Load and transport of products from the store/outlets/pharmacy, etc. to the stock room/warehouse by company vehicle and driver		
4. For consumers: Announce recall on official website and/or social media for <u>Class I and II recalls</u> . Include instructions on how to return the product.		
<i>Extra pages may be attached.</i>		

6. Distributor List Worksheet

Name of Distributor/Retailer	Address	Contact Person	Contact Details	
			Contact Number	Email Address

7. Company Recall Notification

Name of the Company
<p style="text-align: center;"><i>(Insert company letterhead)</i></p> <p style="text-align: center;">URGENT Health Product Recall Notification</p> <p>Date: _____</p> <p>Our Company is recalling <u>(brand name, product name and batch/lot no.)</u> due to <u>(state the reason)</u> as a precautionary measure to protect public health. (note: actual label shall be attached)</p>

***Please follow these instructions to ensure a successful product recall:**

- XXX
- XXX
- XXX

***If you have distributed any of the recalled health products, please immediately**

- **XXX**
- **XXX**
- **XXX**

I appreciate your cooperation. For inquiries regarding this recall feel free to contact (company representative) at (phone number/mobile number).

Respectfully,

(Company Representative)

8. Phone Script

Good day! Our Company is recalling (product name) due to (state the reason) as a precautionary measure to protect public health.

***Please follow these instructions to ensure a successful product recall:**

- XXX
- XXX
- XXX

***If you have distributed any of the recalled health products, please immediately**

- **XXX**
- **XXX**
- **XXX**

I appreciate your cooperation. For inquiries regarding this recall feel free to contact (company representative) at (phone number/mobile number).

9. Recall Notice Worksheet

Name of Distributor/Retailer	Mode of Notification	Date Notified	Date Responded	Quantities Delivered	Quantities Returned	Quantities Not Returned
Total no. of establishments that responded:						
Total no. of establishments that did not respond:						
Total no. of products returned:						
<i>Extra pages may be attached.</i>						

*The Company shall attach proof of returned products

Prepared by:

(Name and signature of Recall Coordinator) (Date)

10. Recall Effectiveness Check Questionnaire shall be conducted by the MAH to verify that all distributors/retailers/consumers of the implicated product at the recall level (whether Trade Level Recall or Consumer Level Recall) received the company notification about the recall and have taken appropriate action.

Recall Effectiveness Check

1. Did your company receive notification from _____ that is recalling its _____ product?
 _____ YES _____ NO

2. Did your company receive shipments of the product being recalled?
 (If no, please sign and return).
 _____ YES _____ NO

3. Do you now have any of the recalled products on hand?
 (Please check inventories before answering).
 _____ YES _____ NO

4. If the answer to question 3 is YES, do you intend to return the product to the (recalling company) as requested?
 _____ YES _____ NO

5. If the answer to question 4 is NO, please explain your intentions

6. Have you received illness or injury reports due to the recalled product?
 _____ YES provide details: _____
 _____ NO

7. Did you ship the recalled product to other distribution, retailers or consignee?
 _____ YES _____ NO

8. If the answer to question 8 is YES, did the distributor/retailer/consignee have any product on hand?
 _____ YES _____ NO _____ NOT SURE

Thank you for your cooperation.

Printed Name and Signature

Position

Date

Company

(*Recalling Company*)

Printed Name and Signature

Date

11. Recall Status Report

Information on the Recalled Product	
Total Number of Products Manufactured under specific batch/lot no.	
Total Number of Products for Recall under specific batch/lot no.	
Date Manufactured	
Date Distributed	
How the product was quarantined	
Method of Quarantining	
Place of Quarantine	
Total Number of Distributors/Retailers/Consignees	
Total Number of Repackers/Manufacturers (if applicable)	
Total number of foreign consignees (if applicable)	
Total Number of Government agencies involved (if applicable)	
Recall Strategy	
Recall Depth	
Communication Method including Media Announcement through social media pages, etc.	
Phone script, letter, email drafts	

12. Request Form. This request shall be submitted to the FDA CFRR when requesting for an FDA Officer to witness the destruction/return of recalled products

Request for FDA Food-Drug Regulation Officer to Witness Destruction/Return/Redress of Recalled Products	
Date of actual Destruction/Return:	Time:
DENR-accredited third-party waste treatment facility:	
_____ Port of Exit (If Return): _____	

Address: _____

Final inventory/number of recalled products for destruction:

Grand Total		

Requesting Party: _____

Company Name

Company Representative: _____ Date: _____

Printed Name and Signature

Mobile number and email address: _____

13. Product Disposition Form. The MAH shall fill up the form by placing a check on the type of disposition conducted

Product Disposition	
Type of Disposition	Remarks