



Recall Manual  
Norax Supplements

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## FDA RECALL CLASSES DEFINED

When the US Food and Drug Administration (FDA) recalls a product, they classify it into three classes based on the relative health risk: Regardless of the classification level of a recall, consumers are advised to take each of them seriously and follow the instructions provided by the agency responsible for the recall.

- **Market withdrawal:** When a product has a minor violation that would not be subject to FDA legal action. The company removes the product from the market or corrects the violation. In some cases, it's also referred to as the process of retrieving the suspected product from the **distributor** end.
- **Recalls:** Actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority. In some cases, it's also referred to as the process of retrieving the suspected product from the **consumer** end.

Note: In some GFSI standards withdrawal and recalls are interchangeable terms

**Class I:** There is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. This is the most severe type

*Examples are:*

1. Listeria Monocytogenes in food products
2. Undeclared allergens in food item

**Class II:** Use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or the probability of serious adverse health consequences is remote.

*Examples are:*

1. Wash water solution in mixing bowl
2. Metal or glass fragments found in a product

**Class III:** Use of or exposure to a violative product is not likely to cause adverse health consequences. Commonly issued due to quality issues

*Examples are:*

1. Mislabeling of flavors or non-allergenic ingredients
2. Noncompliant type size or label layout

## Recall Team

Assignment	Person	Contact Information
Public Notification (to CB and SQFI within 24 hours of public notification)	Chad Hinson	Cell #: 864-377-4838
Publicity and Public Relations Alternate:	Chad Hinson	Cell #: 864-377-4838
Sales & Marketing Alternate:	Chad Hinson	Cell #: 864-377-4838
Expert Advise	Intertek Alchemy Nathan Guzman	email: Nathan.guzman@alchemysystems.com Mobile: 901-395-6746
Logistics and Receiving Alternate:	Kayla Faust	OFFICE: Cell#: 509-389-6053
Quality Assurance Alternate:	Kayla Faust	OFFICE: Cell #: 509-389-6053
Accountant & Admin Alternate:	Kayla Faust	OFFICE: Cell#: 509-389-6053
<ul style="list-style-type: none"> <li>FDA Recall Coordination</li> <li>Georgia Dept. of Agriculture</li> </ul>	Contact for: Product Recalls	Emma Nesbit, Recall Coordinator, Atlanta District, 404-253-1293, <a href="mailto:orahafeast3recalls@fda.hhs.gov">orahafeast3recalls@fda.hhs.gov</a>  Natalie Adan, GDA Food Safety Director, 404-657-4801, <a href="mailto:Natalie.Adan@agr.georgia.gov">Natalie.Adan@agr.georgia.gov</a>

## Determining if a Recall Action Necessary:

Upon the discovery of a possible issue with a finished product, the following questions need to be answered:

### Identity of the product in question:

1. What products are involved (varieties, sizes, etc.)?
2. What are the lot codes and production dates of affected product?
3. At what facility were the items produced?

### Reason for the product to be of questionable quality:

1. What type of defect?

2. What is the cause of defect (if known)?
3. How was the problem discovered?

**The potential health hazards:**

1. Were any illnesses or injuries reported?
2. What hazards could result from the problem?
3. How severe is the problem to public health?
4. What is the worst case scenario for a person consuming this product?

**Quantity of the product in question:**

1. Which production lines and what shifts were involved?
2. What quantities were produced?

**What customers received this product?**

1. Identify all known destinations of the affected product.

Was distribution of the product restricted to certain geographies, distributors, or retailers?

In addition to the steps above, Norax may use the following chart to aid in the decision making whether or not a recall must be initiated:

<b>Problem reported by</b>	<b>Initial Action</b>	<b>Decisions</b>	<b>Actions</b>
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	<b>If no recall is needed:</b> Document why not and action.
News media story on problem with a type of food you produce	Assemble recall team, review internal records		<b>If recall is needed:</b>
Internal QC or customer information suggest a potential problem	Assemble recall team and review internal records		<ul style="list-style-type: none"> <li>• Assign responsibilities</li> <li>• Gather evidence</li> <li>• Analyze evidence</li> <li>• Get word out</li> <li>• Monitor recall</li> <li>• Dispose of product</li> <li>• Apply for termination of recall</li> </ul>
Health Department believes your product is causing illness	Assemble recall team, contact appropriate regulatory agency		

			<ul style="list-style-type: none"> <li>• Assemble recall team and debrief</li> <li>• Prepare for legal issues</li> </ul>
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**Notification Phase**

If a Class I Recall is warranted, the first group to be notified is the US Food and Drug Administration (FDA), **Georgia Department of Agriculture** any other state regulatory agencies into which the product was shipped. A Class I Recall also requires notification to the media in the affected marketing areas. A press release should be prepared before any contacts are made. The purpose of a prepared press release is to avoid any confusion or misinterpretation of the situation.

Complete a Reportable Food Registry (RFR) using your facility's food registry number online at [www.fda.gov/food/complianceenforcement/rfr/](http://www.fda.gov/food/complianceenforcement/rfr/). Some fields may be left blank initially and amended later as more information becomes available. For help, contact [RFRSupport@fda.hhs.gov](mailto:RFRSupport@fda.hhs.gov) or [RFRTechSupport@fda.hhs.gov](mailto:RFRTechSupport@fda.hhs.gov).

In the event of any recall, a list of talking points should be developed. This is to include what facts are known and what corrective action has taken place. These will be the only facts that will be discussed with consumers and customers. The only information to be shared should come from the list of talking points developed by the committee. All employees also need to be informed of the situation following the above rules.

If possible, sequence of notification should be determined by the quantities received. Notification can be by means of telephone, email, or personal contact. The severity of the recall will determine which method is used.

These responsibilities are outlined below:

- \* Michael Gregory will be the contact person for media interviews. The alternate spokesperson will be 3<sup>rd</sup> party media relations specialist.
- \* Steven Ray will contact the FDA and report to the Reportable Food Registry.
- \* Steven Ray - SQFP will inform Norax employees of the situation.
  
- \* Michael Gregory will notify the media of the recall and set up any interviews.
- \* Steven Ray and/or trained designated employee will lead the effort to obtain the necessary documentation.
- \* All appropriate media outlets will be emailed a formal press release.
  
- \* Regardless of which method is used, each person making contact with the media or customers must keep a written report outlining who was contacted and time and date of contact.

## Mock Recall Procedures and Check List

1. Confirm that the Recall Committee information is up-to-date.
2. Verify that the appropriate press release templates are available and that the person responsible knows how to use them.
3. Be sure that the names and phone numbers of customers who need to be contacted are available and current.
4. Identify regulators who need to be contacted and their phone numbers if the recall scenario occurred.
5. Identify the problem and assess the health risks.
6. Determine the products and lot numbers involved. This should include the product name, UPC, lot code(s), and Best By date(s).
7. Determine the production day, shifts, and all employees involved.
8. Determine quantities produced.
9. Determine the current inventory in-house.
10. Determine the amount of product in the marketplace.
11. Identify the customers who have received the product.
12. Generate a recall memo to be given to the media. Also develop talking points to be used by sales representatives and other employees.
13. Generate a call list for the customers to be contacted.
14. Collect Quality Control records, COAs, and other pertinent documentation.
15. Identify which regulatory authorities should be called.
16. Identify which media sources should be called.
17. For each of the aforementioned items, establish the times necessary to gather the information. The target timeframe is four hours maximum.
18. Determine the percent effectiveness of the mock recall using this formula:
  - A – Total amount of product produced
  - B – Amount still on inventory
  - C – Amount delivered to customers
  - D – Incidental usage (lab samples, etc.)
$$\frac{B + C + D}{A} \times 100 = \% \text{ Effectiveness}$$
19. Outline the shortcomings in our recall plan and what corrective action will be taken. This would include taking longer than four hours to gather the information and/or not being able to potentially account for 100% of the products produced.
20. Mock Recalls should be executed every six months

## 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-xxx Fax: xxx-xxx-xxxx email: xxxxxxxxxx
Public contact:	<i>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</i>	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: <ul style="list-style-type: none"><li>• Date of complaint</li><li>• Description of complaint -include details of any injury or illness</li><li>• Lot Number involved</li></ul>	
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 <ul style="list-style-type: none"> <li>• distributor level</li> <li>• customer level</li> </ul>	
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 <b>was</b> shipped?	Recalled product <b>was</b> sold?	Recalled product <b>may</b> 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



**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](http://www.xxx.com)