Please provide detail information regarding the recall **(please follow the format below and describe items in <u>detail</u>)**:

1 <u>PRODUCT(S)</u>: please include:

- Name of product:
- Brand name:
- Unit size (1/2 gallon, 18 ounce, 2 lb. pkgs.):
- Container description (in paper cartons, in glass jars)
- Total package size (i.e. 12 individual items per case)
- Storage instructions, if any (frozen, refrigerate after opening etc.)
- Date(s) of manufacture (when to when, i.e. 12/15/00 to 03/30/00)

2. <u>CODE(S)</u>:

- List all batch numbers, lot numbers and/or serial numbers, product numbers, catalog numbers, packer or manufacturer numbers, pull date / expiration. date, etc.

3. <u>FIRMS INVOLVED</u>

- **Recalling firm** - Provide complete name and address of your firm. (include full name, full address, telephone and fax number.)
- **Manufacturer** - Provide complete name and address of manufacturer, if different from recalling firm. (include full name, full address, telephone and fax number.

4. <u>REASON FOR RECALL</u>

- State simply **WHY** your firm decided to recall the product(s).
- How did your firm **DISCOVER THE REASON** for recall [problem description]?
- What is the **ROOT CAUSE** of the reason for recall?
  (Include any analytical finding in qualitative and/or quantitative terms, indicating whether your firm's analysis or private laboratory was involved. Provide copies of test results/lab. results, Analytical Work Sheets, methodology used, if any.)
- Is the root cause of the problem related to:
  (i) **STERILITY** deficiency : YES [ ] NO [ ]
  (ii) **PACKAGING** deficiency: YES [ ] NO [ ]
- What type of **ILLNESS or INJURY** may be caused by the problem?
- What is the **TOTAL** number of reports of **ILLNESS or INJURY COMPLAINTS** received regarding recall product?
  (Please provide copies of such report.)
- What is the **TOTAL** number of reports of **PRODUCT DEFECT COMPLAINTS** received regarding the recall product?
  (Please provide copies of such report.)
- Have you done any **HEALTH HAZARD EVALUATIONS** and/or Health Risk Assessments associated with the recall product?
  (i.e. No health consequences, minor/major health consequences, potential serious risk of patient injury, potential risk of a serious or life threatening allergic reaction/DEATH!)
- List corrective measures taken to **PREVENT SIMILAR OCCURRENCE** of the problem. (Include copies of documents pertaining to Engineering Change Orders (devices),

verification of training or SOP changes, documents pertaining to product QA, design control, specifications, validation of software, etc.)

5. VOLUME OF PRODUCT IN COMMERCE
   - What is the TOTAL amount of recall product that was **manufactured**?
   - What is the TOTAL amount of recall product distributed in **commerce**?
   - What is the TOTAL amount of recall product **remaining** at your firm?
   - What were the **DATES** of distribution?
     when to when (i.e. 1/14/00 to 4/15/00)
   - Provide an **ESTIMATE** (%) of the amount of product that may be recovered.

6. DISTRIBUTION PATTERN
   - What is the TOTAL number of **consignees** (customers) that received the recall product?
   - What is the TOTAL number of **wholesaler dealers** that received the recall product?
   - What is the TOTAL number of **distributors** that received the recall product?
   - What is the TOTAL number of **retailers** that received the recall product?
   - Where is the recall product **distributed**?
     (Indicate worldwide/nationwide/statewide and **name the U.S. States,** e.g., CA, NV,**)**

Provide a list of the consignees with their FULL ADDRESSES with PHONE NUMBERS

Was any product distributed to U.S. Defense supply Centers, VA, Other Federal Governmental Agency or Foreign countries? If so, provide list of Foreign / Governmental consignees in a separate list will full addresses.

7. FIRM'S RECALL STRATEGY

The following questions are provided to assist you in describing your recall strategy in **DETAIL** as follows:

- Include the **DATE** recall was initiated, if it is already underway or the DATE your firm plans to start the recalling process.
- How do you plan to **NOTIFY** all the consignees affected by this recall?
  (press release, letter, fax, telephone, e-mail, visit, etc.)
- How do you plan to undertake a **SUB-RECALL**?
  If the product is distributed to wholesale dealers/distributors/retailers will you provide follow-up letters to wholesalers? i.e. wholesalers are requested to forward copies of your recall letters and response forms to their customers, etc.)
- How do you plan to monitor the number of consignees **NON-RESPONDING** to the recall communication?
  (include envelopes and return/reply cards, via response form mailed, certified mailing with return receipt, visit, telephone follow-up call, etc.)
- How do you plan to do **EFFECTIVENESS CHECKS** of this recall?
  (by response form mailed?, certified mailing with return receipt, follow-up with telephone, email, visit, letter, etc.?)
- Date your firm ceased further distribution of the product(s).
- How do you plan to **STORE** the recall product, if returned? (quarantine, locked stored, etc.)

[NOTE: It is equally important to assure that all returned merchandise is promptly inventoried, handled, and stored in such a manner as to assure its separation from acceptable materials so it will not inadvertently be used or shipped. Our past experience in similar situations has shown that the longer a defective product is held between the initiation and termination of a recall, the greater the chance of its accidental misuse.]

- How do you plan to **DISPOSE** the recall products?
  (destroy, recondition, correct label, field correct by firm's personnel, etc.)

Please Note: Any destruction or reconditioning of recalled items may require FDA supervision.

8. FIRM OFFICIALS
   - Who is the **most responsible** individual for the firm that is located in the U.S. (i.e. President, CEO, etc.)?
   - Who is the **recall contact** person that will be dealing with FDA?
   - Who is the **public contact**? (Note: this could be an individual person as well as a department such as Customer Service.)

Please include proper names, Titles, complete address with city, state and zip and phone numbers and email address.

PLEASE PROVIDE THE FOLLOWING DOCUMENTS:

- **PRODUCT LABEL(s):** including immediate product label, box labeling and any associated labeling
- **CUSTOMER LETTER(s):** including Notification Letter(s) to consignees, phone scripts, recall letter(s) or voluntary recall letter(s)
- **PRESS RELEASE:** News release, allergy alert, if any
- **DISTRIBUTION LIST:** List of consignees / customers, include full street address and phone numbers
- **DOCUMENT(s):** (Health Risk Assessment, Product QA, Specification Sheet, SOP changes, complaint follow-up investigation, etc.)
- **TEST RESULT(s):** Analytical Work Sheet, Failure Analysis Worksheet, Lab. results, etc. and methodology used)

Please address all your correspondence regarding this matter to

Kristy Zuroski, Recall Coordinator, 612-758-7120
kristine.zuroski@fda.hhs.gov

For correspondence sent via **USPS / Fed Ex / UPS**

U.S. FDA - Minneapolis District
250 Marquette Avenue South, Suite 600
Minneapolis, MN 55401

Or via **facsimile** at 612-334-4134

Thank you for your cooperation and efforts.

Kristy Zuroski

Finding Recall Guidance on website

www.fda.gov

to look up recent posted press releases, click on "Recall & Safety Alerts" middle of home page.

At the end of that list under

Additional Resources You can click on **"Industry Recall Guidance"**

Industry Guidance
Information on Recalls of FDA Regulated Products

Last Update: 12-14-2011

- Industry Recall Guidance[1]: Product Recalls, Including Removals and Corrections
- Recalls Background and Definitions[2]
- Index of Model Press Releases:
    - Allergens[3] (Allergy Alert)
    - Listeria monocytogenes[4]
    - Clostridium botulinum[5]
    - Salmonella[6] (all serotypes)
        - Pet Food and Pet Treats[7]
    - E. coli[8] 0157:H7
    - Medical Device[9]
    - Human Drug[10]
- District Recall Coordinators[11]
- Index of Model Letter Exhibits in FDA Regulatory Procedures Manual:
    - 7-1 - Effectiveness Check Letter[12]
    - 7-2 - Effectiveness Check Response Format[13]
    - 7-3 - Effectiveness Check Questionnaire[14]
    - 7-4 - Recall Letter (generic)[15]
    - 7-5 - Recall Return Response Form[16]
    - 7-6 - Recall Envelope[17]
- Assisting Interested Parties in Addressing Marketplace Confusion Over the Identity of Products Subject to Recall[18]

Additionally you can click on "A to Z index" at top of page.
Then click letter "R"
Then click on "Industry Guidance" under Recalls