If your recall only extends to the wholesale/distributor level, we recommend that you explain your rationale for not recalling to retail/pharmacy level.

- Indicate the method of notification (i.e. mail, phone, facsimile, e-mail). It is advisable to include a written notification so customers will have a record of the recall and your instructions.
- Indicate how letters will be sent to customers (e.g. overnight mail, first class mail, certified mail, facsimile)
- If initial notification is by phone, provide a copy of the phone script to FDA.
- If you have a web site, you should consider posting the recall notification on the web site as an additional method of recall notification. (Note: This is not recommended as a sole means of customer notification.)
- Report on what you have instructed customers to do with the recalled product.
- It is helpful for recalling firms to know the name and title of the Recall Contact for each of its consignees. Addressing a recall notification letter to a recall contact will expedite the recall process and reduce the potential for the notification letter to get misdirected.
- If product is to be returned, explain the mechanics of the process.
- Explain if this recall will create a market shortage that will impact on the consumer.
- Report on recall effectiveness check strategy. Include your actions for non- responders. See: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm>
- Determine and provide your course of action for out-of-business distributors.
- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. Please provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable CGMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.

In addition, we recommend 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.
- The recalling firm and customers keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, (i.e. product relabeling), be performed by recalling firm representatives, or under their supervision and control. It is not recommended that a disinterested party such as a wholesaler or retailer be responsible for field corrections. For Drug Recalls: Misbranded drugs for re-labeling should be returned to the recalling firm.
- You contact your local District Recall Coordinator prior to release of reconditioned goods.

B. Public Notification

1. PRESS RELEASE:

In a situation where the product may pose a significant health hazard and recalled product is in the hands of consumers, a press release is usually appropriate. Issuance of a press release should be the highest priority and it should be issued promptly . Unique situations will be handled on a case-by-case basis.

- You should consult with your local District Recall Coordinator before issuance of a press release

whenever possible. A joint press release may benefit the firm and FDA by alerting the public to a serious health hazard or situations deemed to be in the public interest. Model Press Releas Guidance is available on the FDA website at: http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html

- To assure the broadest coverage, press releases should be issued through the Associated Press (AP). For local and/or regional recalled product distribution, you should contact the Associated Press offices in the States in which the product was distributed. Associated Press contacts can also be found on their website at: www.ap.org. Click on "Contact AP" at top of the home page. For recall press releases needing national media coverage (8 states or more), firms should call the Associated Press, Washington, DC Bureau at 202-776-9467 during business hours. After 5:00 p.m. Eastern time, contact the AP news desk at 202-776-9477. The facsimile number is 202-776-9570. Your local District Recall Coordinator can offer guidance.

NOTE: For those recalls where FDA believes a Press Release is warranted, the Agency will issue a Press Release if the firm has failed to do so, or if the firm-initiated press release is not adequate.

2. GUIDANCE FOR WRITTEN RECALL NOTIFICATION LETTERS: Recall Notifications should be flagged in large bold print "URGENT: [insert "FOOD", "DRUG", "MEDICAL DEVICE", etc.] RECALL or CORRECTION". Envelopes should be similarly flagged. FDA recommends that you include the following information in a recall notification:

a. PRODUCT IDENTIFICATION:

- Include an accurate and complete description of the product and any codes used to identify the product, e.g. lot/unit numbers, expiration date, serial numbers, catalog numbers, model numbers, and UPC codes.
- Consider including a copy of the product label with the recall notification. This could be helpful for wholesalers and retailers in identifying and removing the recalled product.

b. DESCRIPTION OF THE PROBLEM:

- Identify the problem and any potential health hazard(s) associated with it.

c. DEPTH OF THE RECALL:

- The recall notification should clearly identify the depth to which the recall is to extend (e.g. wholesale, retail, or user level). If the recall is to the retail level, a statement should read: "This recall is to the retail level".
- If the product could have been further distributed by your customers, then you should include instructions to subrecall. Subrecall instruction should also include the depth of the recall, e.g. "If you have further distributed this product, you should notify your customers to the retail level."
- If your customers are instructed to conduct subrecalls, it is advisable to provide them with the date range that the recalled product was distributed. Wholesalers/ distributors may r information in order to identify customers they shipped/sold recalled product to.

You should consider providing a subrecall letter with your notification package for your customers to further notify their sub accounts. You are then assuring that the informatio accounts is accurate and complete.

d. INSTRUCTIONS TO CUSTOMERS:

- Your recall INSTRUCTIONS should be clear. For example:
  - Remove product from sale
  - Cease distribution
  - Subrecall (if appropriate)
  - Return product
  - Explain procedure for product correction
- Include a RETURN RESPONSE card/form. This return response card/form should include all instructions from your recall letter. Your customers should be required to indicate that they followed every instruction.

Provide examples of ALL recall communications (include letters, attachments, envelope) to your Local District Recall Coordinator.

IMPORTANT: All customers in the distribution chain should be NOTIFIED of the recall, preferably in writing. Here are some examples of why this is important.

1. In the case of a human drug recall, FDA does not believe it is appropriate for a salesman to visit a doctor's office and remove product without notifying the physician or responsible staff. Physicians may be treating patients that may suffer or have suffered some adverse effect from the drug subject to recall. With knowledge of the recall and the reason for the recall, the physician can better evaluate a patient's condition and provide appropriate patient care.
2. In the case of products sold at retail stores, FDA does not believe it is appropriate for a sal broker representatives to remove product from retail shelves without informing store management of the recall. Failure to inform store management of the recall could result in product that is in storage, in transit to the store, or returned by customers, being offered for sale. The salesmen or broker representatives may not have knowledge or access to the recalled products stored in back rooms. Recalled products that are in-transit to the store would then be sold to customers. Recalled products returned by customers may be placed back on store shelves.

C. Evaluation of the Recall

1. EFFECTIVENESS OF THE RECALL:

It is the recalling firm §¶ responsibility to assure that the recall is effective. Therefore, we recommend that you consider effectiveness checks for every recall. The purpose of an effectiveness check is to verify your recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain.

The effectiveness check is your means of evaluating the effectiveness of your recall. If your effectiveness checks indicate that the recall notification was not received, read and/or instructions followed, then you should take necessary steps to make the recall effective. These steps may involve sending out a follow up notification that better identifies the product, better explains the problem and/or provides better instructions to customers.

Your District Recall Coordinator will provide a copy of a FDA document, ³Methods for

Conducting Recall Effectiveness Checks.

Note: In addition to the effectiveness checks conducted by recalling firms, FDA may also contact a percentage of your customers (referred to as audit checks) as a means of assuring the recalling firm and its consignees are carrying out their recall responsibilities. If FDA's audit checks determine the recall to be ineffective , the recalling firm (or sub recalling firm if such is the case) will then be asked by FDA to take appropriate actions, including re-issuing recall notifications.

2. RECALL STATUS REPORTS:

You will be asked to provide Recall Status Reports after initiating a recall (usually on a monthly basis but more frequently when indicated) to your local District Recall Coordinator. The reports requested will usually include the following information:

- Dates customers notified
- Number of customers notified
- Number of customers responding
- Quantity of RECALLED product returned or accounted for
- Details of your recall effectiveness checks

3. ROOT CAUSE OF THE PROBLEM THAT RESULTED IN THE RECALL:

We recommend that you provide this information to your local District Recall Coordinator once the root cause has been established. It is important to establish the root cause of the problem so that appropriate preventative measures can be taken.

4. CORRECTIVE ACTIONS TO PREVENT FUTURE OCCURRENCES OF THE PROBLEM:

We recommend that you explain the corrective actions planned or underway that will prevent a similar problem from occurring. We further recommend that you provide this information to your local District Recall Coordinator when it has been established.

5. TERMINATION OF THE RECALL:

We recommend that you evaluate your recall for termination when all possible customer responses have been received and it is reasonable to assume that the recalled product has been recovered, corrected, reconditioned, or destroyed. A final status report and documentation of recalled product disposition should be provided to your local District Recall Coordinator before FDA will consider formal termination of the recall action. See:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?FR=7.55

Note: Upon receipt of necessary termination information, the district recall coordinator will prepare a recall termination document for Center and/or district management concurrence. When concurrence is obtained, the district office will notify the recalling firm that FDA considers the recall terminated.

Additional Guidance and/or Requirements:

21CFR Part 7, Subparts A and C - Recalls - General guidelines
21CFR Part 107, Subpart E - Mandatory recall of Infant Formula
21 CFR Part 1270 - Human Tissue
PHS Act - 42 U.S.C. 262 - Mandatory recall of biological products
21 CFR Part 806 - Medical Device Corrections and Removals
FD&C Act, 518(e) - Mandatory Device Recalls

FDA DISTRICT RECALL COORDINATORS

A current list of FDA recall coordinators can be found on FDA ¶ website at:
http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html#recall

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