

7-1 RECALL COMMUNICATIONS EXAMPLE

MODEL DRUG RECALL LETTER

[Company Letterhead]

(in red print) URGENT: DRUG RECALL – Nonsterile injectable

[Date]

[Contact name or Department]

[Firm Name]

[Address]

Dear [wholesaler, retailer, consumer]:

This is to inform you of a product recall involving: [Brand Name (generic) dosage form, strength, description and size of packaging, NDC or UPC codes, lot numbers]

See enclosed product label for ease in identifying the product at the [wholesale/ retail/ user level].

This recall has been initiated due to [describe problem and how it was discovered]. [Use/Consumption] of this product may [describe any potential health hazard].

This product was shipped between [range of distribution dates] or This product was shipped to you on [date]. [If possible, provide consignee with shipping dates and quantities shipped.]

Immediately examine your inventory and quarantine product subject to recall. [If this is a retail or user level recall, include the following] In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter [or Enclosed is a letter you should use in notifying your customers should you choose to create a separate letter.]

[Your notification must include instructions on what customers should do with the recalled product.]

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information. If you have any questions, call [name] at [phone number] [days of week] between [start time] am to [end time] pm [state time zone].

This recall is being made with the knowledge of the U.S. Food and Drug Administration. The FDA has classified this recall as class _____ (if classified).

We appreciate your assistance.

John Doe
President

PLEASE FILL OUT AND RETURN

We do not have any stock of List 1234, Cyanocobalamin

Injection Lot No. 4321 on hand

We have requested our accounts to return their stocks of this merchandise to us.

We are returning _____ bottles of List 1234, Lot No. 4321

Name _____

Address _____

First Class
Permit No. 2

BUSINESS REPLY MAIL

No Postage Stamp Necessary if mailed in U.S.A.

Postage will be paid by:

JOHN DOE LABORATORIES
Somewhere, U.S.A. 12345-0909

Henry Doe