This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

METHODS FOR CONDUCTING

RECALL EFFECTIVENESS CHECKS

Prepared by

The Food and Drug Administration

June 16, 1978

EXHIBIT A

Consignee
Name and Address

Date

(Pressure Sensitive
Label)

Dear Sir:

On (date), you were notified by letter that John Doe Company, Someplace, Somewhere 12345, is recalling (product name), container size, code number. All products were manufactured by John Doe Company and distributed solely under the manufacturer's label.

Recall of the product was initiated following a change in their formulation which resulted in products in distribution channels having the same brand name but different ingredients. The old formulation contained X and there is concern that consumers may receive the old formula. Use of the old formulation by such consumers represents a potential health hazard.

The recall notice from John Doe Company requested consignees (wholesalers and retailers) to hold and discontinue selling their existing stock of the old formulations, and return existing inventories of the recalled formulations to John Doe Company.

In order to advise the Food and Drug Administration about the effectiveness of this John Doe Company recall, you are requested to complete and return the enclosed questionnaire promptly using the pre-paid self-addressed envelope.

If you have any questions or problems with this request, please call (name and telephone number).

Thank you for your cooperation.

Sincerely,

NOTE: If this letter is sent to distributors who may have sold the product to retail outlets, a request should be included in the above letter to have such distributors notify their customers as to the status of the product(s) in question.

METHODS FOR CONDUCTING RECALL EFFECTIVENESS CHECKS

INTRODUCTION

In the Federal Register of June 16, 1978, (43FR26202), the Food and Drug Administration (FDA) issued as a final rule, Recalls (including product corrections) -- guidelines on policy, procedures, and industry responsibilities. Section 7.42(b)(3) of these guidelines states that the recalling firm will ordinarily be responsible for conducting recall effectiveness checks. Such checks are for the purpose of verifying that the recalling firm's consignees have received notification about the recall and have taken appropriate action.

To assist the recalling firm in carrying-out this responsibility and in accordance with section 7.42(b)(3) of the FDA recall guidelines, the following may be used as a guide on how to use different methods for conducting recall effectiveness checks. The methods described include mail, telephone calls, personal visits, and combinations of these alternatives. Each of these methods has been tested by FDA and the results have been analyzed in a report available through the National Technical Information Service, 5285 Port Royal Road, Springfield, Virginia, 22161 (Order #277-174/AS).

METHODS

1. General

All the methods for conducting recall effectiveness checks have several common aspects: a consignee list, a common identifier, a questionnaire, and a procedure for recording responses.

A consignee list is to be prepared when a recall is initiated by a firm. Each of the consignees notified of the recall is, therefore, a candidate for a recall effectiveness check. However, if there is suitable documentation that a consignee has been notified and has either made the proper disposition of the recalled product or has submitted a negative report on having the product, it may not be necessary to perform a recall effectiveness check at this consignee.

In order to minimize problems in correlating responses from consignees to the consignee list, each consignee on the list should be assigned a unique number which will serve as the common identifier. The consignee's zip code can be used as part of the number.

In conducting a recall effectiveness check, there are certain basic questions that consignees should be asked. The purpose of these questions is to determine whether: the recall notification was received, the product involved was handled as instructed in the recall notification, the product was further distributed by the consignee before receipt of

the recall notification, and if so, were these additional consignees notified. Other questions may need to be asked depending upon the nature of the recall. Also the design and format of the questionnaire may vary depending upon which method of contact is to be used.

Pressure sensitive labels should be prepared for each consignee which contain the name, address, and number assigned to that consignee. The number of such labels required for each consignee will vary according to which method is used, i.e. five labels for mail (if two mailings are used), and two for telephone calls and personal visits. For all methods, one of the labels is to be placed on a 3x5 card to be used as a control file. The second label is to be used for the consignee's questionnaire.

As a questionnaire is returned and/or completed, it is placed with the control file card for that consignee for "logging in" purposes.

2. Mail

There are four elements to the use of mail:

a. a letter to the consignee,

b. an envelope prominently inscribed with "IMPORTANT RECALL INFORMATION INSIDE,"

c. a questionnaire, and

d. a self-addressed stamped envelope for the consignee to return the completed questionnaire.

The letter to the consignee should state exactly the reason for the recall, a complete description of the product being recalled or corrected, instructions as to disposition of the recalled product, and a request for cooperation in completing and returning the questionnaire. Exhibit A provides an example of the type letter that can be used. An example of the questionnaire to accompany the effectiveness check letter is shown as Exhibit B. It should be noted that the exhibit questionnaires are only examples and that actual circumstances may necessitate changes in the questionnaire wording. Some pretesting of the questionnaire prior to mass mailing is also suggested.

Upon receipt of the completed questionnaires and after "logging in," a master file should be prepared to identify responding consignees by their unique identification number and to record their answers to the questions.

About 2-3 weeks after the first mailing, a follow-up mailing should be sent to the consignees who did not respond to the first mailing. Upon receipt of the completed questionnaires from the second mailing, the same procedure as used previously should be used to log the questionnaires and to record the answers to the questions asked.

Note: A telephone follow-up to the non-respondents and non-deliverable letters from the first mailing may be made instead of a second mailing. Similiarly, the non-respondents from the second mailing and the questionnaires from both mailings which were returned as undeliverable, comprise the consignee list for the telephone follow-up if two mailings are used. Further information about the telephone method is given in the next section.

3. Telephone

The consignee list for the telephone method is the same as the mail contact method except when it is used as a follow-up to the mail method.

Interviewers doing the telephone effectiveness checks should be thoroughly knowledgable about the background and purpose of the recall. Each interviewer should also be given a detailed question-by-question review of the questionnaire. An example of a telephone questionnaire is shown as Exhibit C.

Completed questionnaires are logged as under section 2, including preparation of a master file on the replies.

4. Personal Visit

This method is much like the telephone method in that you are actively questioning a responsible person. The same type of knowledge about the background and purpose of the recall is required by the interviewer. The questionnaire shown in Exhibit C also can be used for personal visits with some modification; the interviewer should be familiar with the questionnaire.

This method has several advantages over the other methods in that:

1. a concrete disposition can be made of the status of each consignee, i.e., if the firm has moved, one can probably determine the new address and complete the interview; or establish that the firm is out of business, and

2. the interviewer can sometimes (depending on the product and type of consignee) look on the shelves and other locations to see if the product has been removed or corrected as a check on the answers.

When the disposition of each firm has been determined and the questionnaires completed, the responses should be logged and compiled as in the other methods.

5. Assessing Recall Effectiveness

Periodic status reports should be prepared by the recalling firm on the progress of the recall effectiveness checks. These reports are also helpful in determining if there is any problem with the questionnaire or the checks at an early stage.

Any reports of illness or injury should be reported to a responsible firm official immediately upon receipt so that arrangements for immediate follow-up can be made.

When the last of the recall effectiveness checks have been made, a final tabulation of the results of the contacts and questionnaires should be made. Evaluation of this data and the results of the recall should give an estimate of the effectiveness of the recall.

Consignee Name and Address
(Pressure Sensitive Label)

EXHIBIT B

Recall Effectiveness
Checks-Mail Method

JOHN DOE PRODUCT RECALL

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

DATE_____

1. Did your firm receive notification that the John Doe Company is recalling its _____(Name)_____ product?

   YES_____ NO_____

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

   YES_____ NO_____

3. Do you now have any of the recalled product 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 John Doe Company as requested?

   YES_____ NO_____

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

   _____

6. Have you received any reports of illness or injury related to this product?

   YES_____ NO_____

   If yes, please provide details.

Name of person completing questionnaire:

_____

Title:

IF YOU HAVE ANY FURTHER QUESTIONS,
PLEASE CONTACT YOUR LOCAL DRUG
WHOLESALER OR THE JOHN DOE COMPANY,
SOMEPLACE, SOMEWHERE
12345

Consignee Name and Address
(Pressure Sensitive Label)

EXHIBIT C

Recall Effectiveness Checks-Telephone and Personal Visits

JOHN DOE PRODUCT RECALL

After contacting the consignee and locating the person responsible for handling recall notifications and/or the product involved, an opening similar to the following may be used:

This is (Name of Interviewer). I am calling for (recalling firm) to check on the effectiveness of the company recall of (product description, including codes). On (date), (recalling firm) notified (how: letter, telephone, visit, mailgram, etc.), all firms which may have purchased (product) that all stock should be (returned, destroyed, modified, relabeled, etc.). I have the following questions to ask you about this recall:

DATE_____

1. Did your firm receive notification that (product name) products manufactured by John Doe Company are being recalled?

   YES_____ NO_____

2. Did your firm receive shipments of the product being recalled? (If no, terminate questioning and go to the closing).

   YES_____ NO_____

3. Do you have any of the recalled product 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 John Doe Company as requested?

   YES_____ NO_____

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

   _____.

6. Have you received any reports of illness or injury related to this product?

   YES_____ NO_____

If yes, please provide details.

Thank you for your cooperation.

And your name is _____

And what is your title please? _____

Interviewer _____

Date _____

IF RESPONDENT HAS ANY FURTHER QUESTIONS, ASK HIM/HER TO CONTACT THE JOHN DOE COMPANY, SOMEPLACE, SOMEWHERE 12345