

1. RECALL INFORMATION

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|-------------------------|-------------------|---------------------|---------------|
| a. RES/RECALL NUMBER(S) | b. RECALLING FIRM | c. RECALLED CODE(S) | d. PRODUCT(S) |
|-------------------------|-------------------|---------------------|---------------|

2. PROGRAM DATA

| | |
|------------------|---------------------------------|
| a. HOME DISTRICT | b. FEI NUMBER OF RECALLING FIRM |
| c. PAC CODE | d. HOURS |

3. AUDIT ACCOUNTS

| | |
|---------------------------|----------------------------|
| a. DIRECT | b. SUB-ACCOUNT (SECONDARY) |
| PHONE NO.: | PHONE NO.: |
| c. SUB-ACCOUNT (TERTIARY) | |
| PHONE NO. | |

4. CONSIGNEE DATA

| | | |
|---|--|--|
| Contacted by: <input type="checkbox"/> Phone <input type="checkbox"/> Visit <input type="checkbox"/> Other a. NAME OF PERSON CONTACTED & TITLE | b. TYPE CONSIGNEE <input type="checkbox"/> Distributor <input type="checkbox"/> Consumer <input type="checkbox"/> Pharmacy <input type="checkbox"/> Retailer <input type="checkbox"/> Physician <input type="checkbox"/> Restaurant <input type="checkbox"/> Processor <input type="checkbox"/> Hospital <input type="checkbox"/> School <input type="checkbox"/> Other: _____ | c. DOES (DID) THE CONSIGNEE HANDLE RECALLED PRODUCT? <input type="checkbox"/> Yes <input type="checkbox"/> No |
|---|--|--|

5. NOTIFICATION DATA

| | | |
|--|--|---|
| a. FORMAL RECALL NOTICE RECEIVED? (If "No", skip to item 6c.) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Cannot be determined (If answer is other than "No", explain in remarks.) | b. RECALL NOTIFICATION RECEIVED FROM <input type="checkbox"/> Recalling Firm <input type="checkbox"/> Other (Specify below) <input type="checkbox"/> Direct Account <input type="text"/> <input type="checkbox"/> Sub-Account | c. DATE NOTIFIED (mm/dd/yyyy) d. TYPE OF NOTICE RECEIVED (e.g., letter, phone) |
|--|--|---|

6. ACTION AND STATUS DATA

| | | |
|---|--|--|
| a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? (If "No", discuss in "Remarks" action taken upon FDA contact.) <input type="checkbox"/> Yes <input type="checkbox"/> No | c. CURRENT STATUS OF RECALLED ITEMS <input type="checkbox"/> Returned <input type="checkbox"/> None on Hand <input type="checkbox"/> Corrected <input type="checkbox"/> Was Still Held for Sale/Use* <input type="checkbox"/> Destroyed <input type="checkbox"/> Held for Return/Correction* * = Ensure Proper Quarantine/Action | 7. SUB-RECALL NEEDED? Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.) <input type="checkbox"/> Yes <input type="checkbox"/> No |
| b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION | d. DATE AND METHOD OF DISPOSITION | 8. AMOUNT OF RECALLED PRODUCT NOW ON HAND |

9. INJURIES/COMPLAINTS

a. IS CONSIGNEE AWARE OF ANY INJURIES, ILLNESS, OR COMPLAINTS?

Injury Complaint
 Illness None

If answer is other than "None", report details in a separate memo to monitoring district and copy to OEO (HFA-615).

10. REMARKS (Include action taken if product was still available for sale or use.)

| CHECK | | ENDORSEMENT | |
|----------------------------|-------------------------|--|--|
| INVESTIGATOR | SCSO OR R&E COORDINATOR | <input type="checkbox"/> Effective <input type="checkbox"/> Does Not Carry Product <input type="checkbox"/> Ineffective (Indicate level) <input type="checkbox"/> Out of Business <input type="checkbox"/> Recalling Firm <input type="checkbox"/> Consignee <input type="checkbox"/> Other (Specify): _____ | |
| Signature | Signature | | |
| Printed Name | Printed Name | | |
| Date of Check (mm/dd/yyyy) | District | Date of Endorsement (mm/dd/yyyy) | |