

1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)
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2. PROGRAM DATA (FDA Users Only)

a. MONITORING DIVISION	b. FEI NUMBER OF RECALLING FIRM
c. PAC CODE	

3. AUDIT ACCOUNTS

a. DIRECT	b. SUB-ACCOUNT (SECONDARY) (Leave blank if none.)
PHONE NO.:	PHONE NO.:
c. SUB-ACCOUNT (TERTIARY) (Leave blank if none.)	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 RECEIVE RECALLED PRODUCT? <input type="checkbox"/> Yes <input type="checkbox"/> No
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5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? (If answer is other than "Yes", explain in remarks and skip to item 6c.) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Cannot be determined	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 NOTIFICATION RECEIVED (mm/dd/yyyy) d. TYPE OF NOTICE RECEIVED (e.g., letter, phone)
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6. ACTION AND STATUS DATA

a. DID CONSIGNEE FOLLOW THE RECALL INSTRUCTIONS? (If "No", discuss in "Remarks" action taken as a result of audit check.) <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? <input type="checkbox"/> Injury <input type="checkbox"/> Complaint <input type="checkbox"/> Illness <input type="checkbox"/> None <i>If answer is other than "None", collect relevant information, document findings, and route per division procedures.</i>

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

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CHECK

Signature	
Printed Name and Title	
Date of Audit Check (mm/dd/yyyy)	FDA Division

FDA ENDORSEMENT

Signature	<input type="checkbox"/> Effective <input type="checkbox"/> Out of Business <input type="checkbox"/> Ineffective (Indicate level) <input type="checkbox"/> Notifying Firm <input type="checkbox"/> Consignee <input type="checkbox"/> Other (Specify): _____
Printed Name and Title	<i>If "No" is checked for 5a and/or 6a, "Effective" cannot be selected as an Endorsement.</i>
Date of Endorsement (mm/dd/yyyy)	