1. RECALL INFORMATION

a. RES NUMBER	b. RECALLING FIRM	c. RECALLED CODE(S)	d. PRODUCT(S)

2. PROGRAM DATA *(FDA Users Only)*

a. MONITORING DIVISION

b. FEI NUMBER OF RECALLING FIRM

c. PAC CODE

3. AUDIT ACCOUNTS

a. DIRECT

PHONE NO.:

b. SUB-ACCOUNT (SECONDARY) (*Leave blank if none.*)

PHONE NO.:

c. SUB-ACCOUNT (TERTIARY) (*Leave blank if none.*)

PHONE NO.

4. CONSIGNEE DATA

Contacted by: ☐ Phone ☐ Visit ☐ Other

a. NAME OF PERSON CONTACTED & TITLE

b. TYPE CONSIGNEE

☐ Distributor ☐ Consumer ☐ Pharmacy
☐ Retailer ☐ Physician ☐ Restaurant
☐ Processor ☐ Hospital ☐ School
☐ Other: _____

c. DOES (DID) THE CONSIGNEE RECEIVE RECALLED PRODUCT?

☐ Yes ☐ No

5. NOTIFICATION DATA

a. FORMAL RECALL NOTICE RECEIVED? (*If answer is other than "Yes", explain in remarks and skip to item 6c.)*

☐ Yes ☐ No ☐ Cannot be determined

b. RECALL NOTIFICATION RECEIVED FROM

☐ Recalling Firm ☐ Other *(Specify below)*
☐ Direct Account
☐ Sub-Account

c. DATE NOTIFICATION RECEIVED *(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 as a result of audit check.)* ☐ Yes ☐ No

b. AMOUNT OF RECALLED PRODUCT ON HAND AT TIME OF NOTIFICATION

c. CURRENT STATUS OF RECALLED ITEMS

☐ Returned ☐ None on Hand
☐ Corrected ☐ Was Still Held for Sale/Use*
☐ Destroyed ☐ Held for Return/Correction*

* = Ensure Proper Quarantine/Action

d. DATE AND METHOD OF DISPOSITION

7. SUB-RECALL NEEDED?

Did consignee distribute to any other accounts? (If "Yes", collect information and/or provide details in "Remarks" or Memo.) ☐ Yes ☐ No

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", collect relevant information, document findings, and route per division procedures.

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

CHECK		FDA ENDORSEMENT	
Signature		Signature	☐ **Effective** ☐ **Out of Business**
Printed Name and Title		Printed Name and Title	☐ **Ineffective** *(Indicate level)* ☐ *Notifying Firm* ☐ *Consignee* — *If "No" is checked for 5a and/or 6a, "Effective" cannot be selected as an Endorsement.*
Date of Audit Check *(mm/dd/yyyy)*	FDA Division	Date of Endorsement *(mm/dd/yyyy)*	☐ **Other** *(Specify)*: _____

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