Action Log for Recalling Procedure

The Recall Decision

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Recall Team notified of problem			
Recall Team Briefed by legal counsel			
Dept. managers briefed on problem and asked for input			
FDA rules reviewed			
Dept. managers submit records to Recall Team			
Risk evaluated			
Decision made to initiate a:			
Stock Recovery			
Market Withdrawal			
Product Recall			
If decision is internal, FDA is notified			
Team Spokesperson prepares information for public release			
Recall Team approves information for public release			

Immediate Actions

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Product production halted			
Internal investigation begun to determine cause and source			
Product in warehouse segregated and secured			
CSR department briefed on what to tell incoming callers & what info to obtain from them			

Information Gathered

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Identity of product(s)			
Establish the use of reworked or repackaged product(s)			
Product(s) package size			
Product(s) lot number			
Production dates			
Quantity per lot number/date produced			
Quantity in warehouse			
Quantity shipped to customers			
Quantity unaccounted for			

Product Location(s) Determined

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Location of each shipment established			
Quantity shipped to each location verified			
Quantity of product unaccounted for			

Recall Classification and Depth

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Recall Classification assigned by the FDA			
Recall Number(s) assigned by the FDA			
Depth of Recall (either established by the FDA or determined by Recall Team)			
Dept. managers updated about recall classification and depth			

Notification to Outside Groups

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Wholesale distributors notified by phone/fax			
Wholesale distributors notified by mail			
Retailers notified by phone/fax			
Retailers notified by mail			
FDA approves news release copy			
News release sent to media list			
Sales Reps instructed on Recall procedures			
Point-of-sale info prepared for Sales reps to deliver to retail customers			

Product Disposition

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Company and FDA agree on collection and disposition of product			
Decisions made about refund or exchange policies			
Wholesalers informed of product disposition			
Retailers informed of product disposition			
Sales reps assist customers in complying with recall			
Customer Service briefed on refund policy			
Warehouse prepared to receive product			
Warehouse isolating returned product			

Effectiveness Checks

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
FDA Effectiveness Check Level established			
Effectiveness Checks begin			
Finish date established			
Review/evaluate Effectiveness Checks			
Prepare Effectiveness Checks summary			

Recall Termination

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Team undertakes review of Recall			
Recall officially concluded			
FDA notified of Recall completion			
Team receives written conformation from FDA of Recall completion			
Announcement (and thanks needed) to customers about successful end of Recall			

Final Steps

Action	Initiated Initials/Date	Completed Initials/Date	Not Applicable
Recall Team assembles all documents			
Team reviews all procedures and makes recommendations to Senior Management			
Team decides on exact cause of problem			
Team Coordinator writes summary report			
Necessary corrections made			
Final report reviewed; presented to senior management			