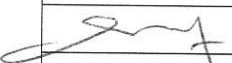
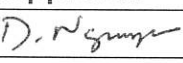
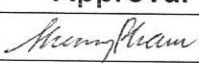


 ROBINSON PHARMA, INC.		Robinson Pharma, Inc., 3330 S. Harbor Blvd., Santa Ana, CA 92704		Procedure No.: SOP 2-009-19	
1 of 15		Product Recall, Market Withdrawal, and Stock Recovery		Effective Date: 08/13/26	
Author	Date	Approval	Date	Approval	Date
	07/28/26		07/28/26		07/29/26
Gulfam Sheikh		Dan Nguyen		Henry Pham	
Director, Quality and Compliance		Director, Customer Service		Director, Quality Control	

1.0 PURPOSE:

- 1.1 To define the procedures for conducting a product recall, market withdrawal, or stock recovery.

2.0 SCOPE:

- 2.1 This procedure applies to raw materials, packaging components, and product(s) manufactured and packaged at all Robinson Pharma, Inc. (RPI) facilities.

3.0 RESPONSIBILITIES:

- 3.1 RPI is responsible for complying with all FDA Enforcement Policy Regulations as related to recall, market withdrawal, or stock recovery.

4.0 DEFINITIONS:

- 4.1 Class I Recall – A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- 4.2 Class II Recall – A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- 4.3 Class III Recall – A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- 4.4 Market Withdrawal – Occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems would be a market withdrawal.
- 4.5 Stock Recovery – A firm's removal or correction of a product that has not been marketed or that has not left the direct control of the firm (i.e. the product is located on the premises owned by, or under the control of, the firm and no portion of the lot has been released for sale or use).

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- 4.6 Mock Recall – Used to determine whether the recall procedure is capable of identifying, tracing and quickly controlling a given lot of potentially affected product and reconciling the quantities produced, quantities in inventory, and quantities distributed. A mock recall will identify potential problems and allow personnel to become familiar with recall procedures.
- 4.7 Recall Review Board (RRB) – A panel consisting of members from Quality Assurance (QA), Operations, Customer Service (CS), Logistics, and Planning appointed to review, evaluate, and determine the severity of the non-conformance and whether a voluntary recall is necessary. The RRB also provides guidance on the recall process if a recall is deemed necessary.
- 4.8 RPI Recall Responder Phone Listing – The 24/7 contact information for key personnel who are part of the Recall Response Team. The phone listing shall be given to each active member, which includes the CEO, Director of Quality Control, Director of Quality and Compliance, CEO Advisor, and Vice President of Sales.
- 4.9 ERP System – Enterprise Resource Planning System
- 4.10 Traceability - The ability to track food through all stages of production, processing and distribution. Traceability movements should be traced, at minimum, one step backward to the supplier and one step forward to the customer.

5.0 FREQUENCY:

- 5.1 This procedure shall be followed every time a product recall, market withdrawal, or stock recovery is necessary.
- 5.2 Mock recalls of raw materials, packaging components, and finished products shall be performed biannually (twice per year), with the exception of any year in which a live recall occurs. Any problems identified in the recall procedures should be corrected.

6.0 NECESSARY EQUIPMENT:

- 6.1 RPI Recall Responder Phone Listing

7.0 PROCEDURE:

- 7.1 Policy Overview

- 7.1.1 Recalls, market withdrawals, and stock recoveries are very unique situations in which the responsible person(s) of a company must act quickly to remove defective product from distribution because the product is in violation (i.e. misbranded or adulterated) of the Federal Food, Drug, and Cosmetic Act. In the most severe cases of recalls (Class I and II), there is a threat to public health and it is important that all company personnel know their responsibilities and act accordingly to protect the public health.

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- 7.1.2 It is the policy of the company to recall or withdraw from the market or distribution channels any product that is in violation of the Federal Food, Drug, and Cosmetic Act.
- 7.1.3 For any situation that is clearly not a health threat and would fall under the FDA classification system as a market withdrawal or stock recovery, the return of product shall be initiated only to those immediate customers and not to any secondary warehouses, retail establishments, or individual consumers.
- 7.1.4 In cases of market withdrawal or stock recovery, the company will remove the product without contacting the FDA. All documentation concerning any market withdrawal or stock recovery should be organized and available in the event that the FDA becomes aware of the situation and requests documentation.
- 7.1.5 It is the policy of the company to conduct a mock recall biannually in order to identify potential problems and evaluate the effectiveness of RPI's traceability of product/material throughout the supply chain.
- 7.1.6 The product(s) being recalled will be rotated between finished goods, packaging components, raw materials, and/or as requested by a customer. An exception to this rule is if a live recall is performed.
- 7.1.7 Records for either a live or mock recall shall be documented in the Recall Summary Report (Attachment 10.2).
- 7.1.8 A mock recall shall be considered successfully completed when all records related to the recalled raw materials, packaging components, and finished goods are retrieved and compiled, along with supporting documentation, within four (4) hours of the recall notification. Any delays in record retrieval or instances of incomplete documentation shall be investigated and documented through the appropriate quality system process, such as a Deviation, Corrective and Preventive Action (CAPA), or Nonconformance Report (NCR).
- 7.2 QA must be notified of any complaint or non-conformance reported by a customer, consumer, regulatory agency, and/or internal sources. All complaints shall be documented, investigated, and maintained in a controlled system. Complaints shall be evaluated to determine if they represent a potential recall, market withdrawal, or stock recovery. Corrective and Preventive Actions (CAPA) shall be initiated where applicable to prevent recurrence and managed in accordance with the CAPA procedure (Reference 8.13).
- 7.3 QA shall determine if the complaint or non-conformance warrants a product recall, market withdrawal, or stock recovery. If a recall is

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warranted, evaluate and determine the recall classification from the definitions in Section 4.0.

- 7.4 The Director of Quality and Compliance or designee shall notify the following Executive Committee Members of a recall:
 - 7.4.1 Chief Executive Officer (CEO)
 - 7.4.2 Vice President of Sales
- 7.5 Assemble the RRB, including any provisional members as needed, and provide the following information to the RRB:
 - 7.5.1 Total amount of product(s) produced and date of production
 - 7.5.2 Other products or lots that may be impacted
 - 7.5.3 Investigation to determine the possible root cause of the non-conformance
- 7.6 CS shall prepare and provide the following:
 - 7.6.1 Distribution data report which provides traceability to the customer and includes the consignee (customer) names, expiration dates, quantities shipped, shipping dates, and lot numbers. (Reference 8.4).
 - 7.6.1.1 Lot numbers provide the complete history of the manufacture, processing, packaging, holding, and distribution of a batch or lot of a finished product or other material. (Reference 8.5).
 - 7.6.2 Tracking reports to capture all affected lots (including lots that were not shipped)
 - 7.6.3 Names and addresses of all corporate customers who may have received the recalled product(s)
 - 7.6.4 Returned Material Authorization (RMA) number
- 7.7 Planning Department shall prepare and provide a report of any on-hand inventory of the lot(s) to the RRB. The inventory control of raw materials, packaging components, and finished goods are maintained by their assigned item numbers. (Reference 8.6).
- 7.8 Logistics Department shall physically place any on-hand inventory of the subject lot(s) in the Quarantine or Rejected Area of the Warehouse and apply quarantine stickers as needed. A list shall be provided to the RRB indicating the quarantine location of each lot.
- 7.9 QA shall quarantine the on-hand inventory implicated with the recall in the ERP System.

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- 7.10 Once it is determined that a recall is necessary and confirmed by the Executive Committee Members of the RRB, QA shall prepare a recall package including the following information as applicable:
- 7.10.1 The Certificate of Analysis (Reference 8.7) or Certificate of Conformance (Reference 8.8) for the identity of the raw material(s), packaging component(s) and/or product(s) involved.
 - 7.10.2 Reason for removal or correction and the date and circumstances under which the raw material, packaging component, and/or product deficiency or possible deficiency was discovered
 - 7.10.3 Evaluation of the risk associated with the deficiency or possible deficiency, taking the following into consideration:
 - 7.10.3.1 Whether any diseases or injuries have already occurred from product use.
 - 7.10.3.2 Whether any existing conditions could contribute to a clinical situation that could expose humans or animals to a health hazard. Any conclusion shall be supported as completely as possible by scientific documentation and/or statements that the conclusion is the opinion of the individual(s) making the health hazard determination.
 - 7.10.3.3 Assessment of hazard to various segments of the population (i.e. children, surgical patients, pets, livestock, etc.) who are expected to be exposed to the product being considered, with particular attention paid to the hazard to those individuals who may be at greatest risk.
 - 7.10.3.4 Assessment of the degree of seriousness of the health hazard to which the populations at risk would be exposed.
 - 7.10.3.5 Assessment of the likelihood of hazard occurrence.
 - 7.10.3.6 Assessment of the consequences (immediate and/or long-term) of hazard occurrence.
 - 7.10.4 Total amount of product(s) produced and/or the time span of production. Documentation of in process checks, verifications, and inspections (located in the batch record) shall be used to identify the status of the product and provide traceability to the inspector or technician. (Reference 8.9).
 - 7.10.5 Total amount of product(s) estimated to be in distribution channels.

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- 7.10.6 Distribution information including the number and, if necessary, identity of direct accounts
- 7.10.7 A copy of the recall communication or a proposed recall communication per 21 CFR 7.49 (a) (b) and (c) (Attachment 10.1)
- 7.10.8 Proposed strategy for conducting the recall
- 7.10.9 Contact name and phone number
- 7.10.10 Recall report to be submitted to FDA
- 7.10.11 Recall notification letters to be provided to corporate customers and third party audit organizations.
- 7.11 Upon confirmation by Executive Committee Members, contact the FDA's Office of Inspections and Investigations (OII) and provide recall information to the appropriate Division Recall Coordinator (see below for contact information).

Product Type	Human Food
Division	Human Food Inspectorate West I
Firm's State	Southern CA (Zip codes covered: 90000-93199, 93400-93499, 93510, and 93532-93539)
Recall Coordinator	Sparky Barte
Contact Information	If a physical mailing address is required to transmit documents to OFRO FREB, please contact us at OIIRecalls@fda.hhs.gov

- 7.12 Mail the recall package to the FDA OII by Overnight Mail.
- 7.13 Mail the recall notification letters to customers by Overnight Mail.
- 7.14 Send the recall notification letters to third party audit organizations (UL, NSF, etc.), including any receipt of warning letter received from the FDA within 7 calendar days.
- 7.15 In the event of a product recall, market withdrawal, warning letter, or significant quality issue involving dietary supplements manufactured at a facility for which a United States Pharmacopeia (USP) certificate has been issued, Quality Assurance (QA) or designee shall notify the United States Pharmacopeia (USP) within five (5) business days of awareness of the event. Records of the notification shall be maintained.

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- 7.16 Based on the information contained in the recall package, the FDA assigns a recall number and classification including an effectiveness check and determines if a public warning is necessary.
- 7.17 Conduct recall effectiveness checks against recall strategy as required by FDA acknowledgement of a voluntary recall. The OII will provide a guidance document on "Methods for Conducting Recall Effectiveness Checks."
- 7.18 Keep track of the following information to provide to the RRB as needed:
- 7.18.1 Number of consignees (customers) notified of the recall, date notified and method used
 - 7.18.2 Number of consignees that responded and the product quantity on hand
 - 7.18.3 Number of consignees that have not responded
 - 7.18.4 Amount of product returned by each consignee and the total amount accounted for
 - 7.18.5 Number and results of effectiveness checks performed. Estimated time frame for completion of recall
- 7.19 Logistics Department shall ensure that all returned products are documented on the "Returned Goods Receiving Report". The returned products shall be labeled "On Hold" and immediately placed in physical quarantine for further processing. Each recalled product receipt must be documented on a separate form. (Reference 8.10).
- NOTE:** Do not dispose of or remove returned products from quarantine without expressed authorization from the Director of Quality and Compliance or designee.
- 7.20 Until recall termination, Logistics Manager will submit copies of all "Recalled Product Receipt" form(s) to the Director of Quality and Compliance or designee.
- 7.21 QA shall determine the disposition of recalled products and issue a memo to the RRB members for destruction or rework of the recalled product as needed.
- 7.21.1 Reprocessing shall be documented in the rework batch record. The product code and lot number issued for the rework batch record is used to provide traceability to the reworked product. (Reference 8.11 and 8.12).
- 7.22 When appropriate, use the information from Section 7.17 to prepare Recall Status Reports per 21 CFR 7.53 for submission to the FDA. If this information is satisfactory, the FDA will terminate the recall.

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- 7.23 Determine the amount of time taken to complete the recall or mock recall. The requirement is to be able to trace 100% of the product, raw material, or packaging component within four hours.
- 7.24 Where a facility becomes aware of a regulatory event pertaining to their firm, UL shall be notified without undue via the UL Online Notification Form. The following events are considered 'regulatory events' requiring notification:
- FDA issued form 483
 - FDA issued warning letter
 - Product recall or market withdrawal
 - Import Alert
 - Field Alert Report
 - Injunction
- 7.25 Whether or not the regulatory event pertains to product under scope, UL shall be notified in order to investigate the potential impact to product under scope. Such notification shall be submitted to UL without undue delay.

8.0 REFERENCES:

- 8.1 21 CFR 7.1 – 7.59 Enforcement Policy on Recalls
- 8.2 FDA Regulatory Procedures Manual: Chapter 7 Recall Procedures
- 8.3 Industry Guidance for Recalls:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls>
- 8.4 SOP 3-003, General Shipping Procedures for Finished Goods
- 8.5 SOP 0-023, Lot Number Logic
- 8.6 SOP 2-021, Creation and Revision of Item Numbers
- 8.7 SOP 1-043, Certificate of Analysis Requirement for Raw Materials
- 8.8 SOP 1-067, Sampling, Testing, and Releasing of Packaging Components
- 8.9 SOP 0-044, Manual Production Process Documentation
- 8.10 SOP 2-010, Customer Returned Product
- 8.11 SOP 0-016, Material Review
- 8.12 SOP 0-054, Product Reprocess Procedure
- 8.13 SOP 2-053, Corrective and Preventive Action (CAPA) Program

9.0 ACTION DIAGRAM:

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9.1 Recall Process Flow Diagram

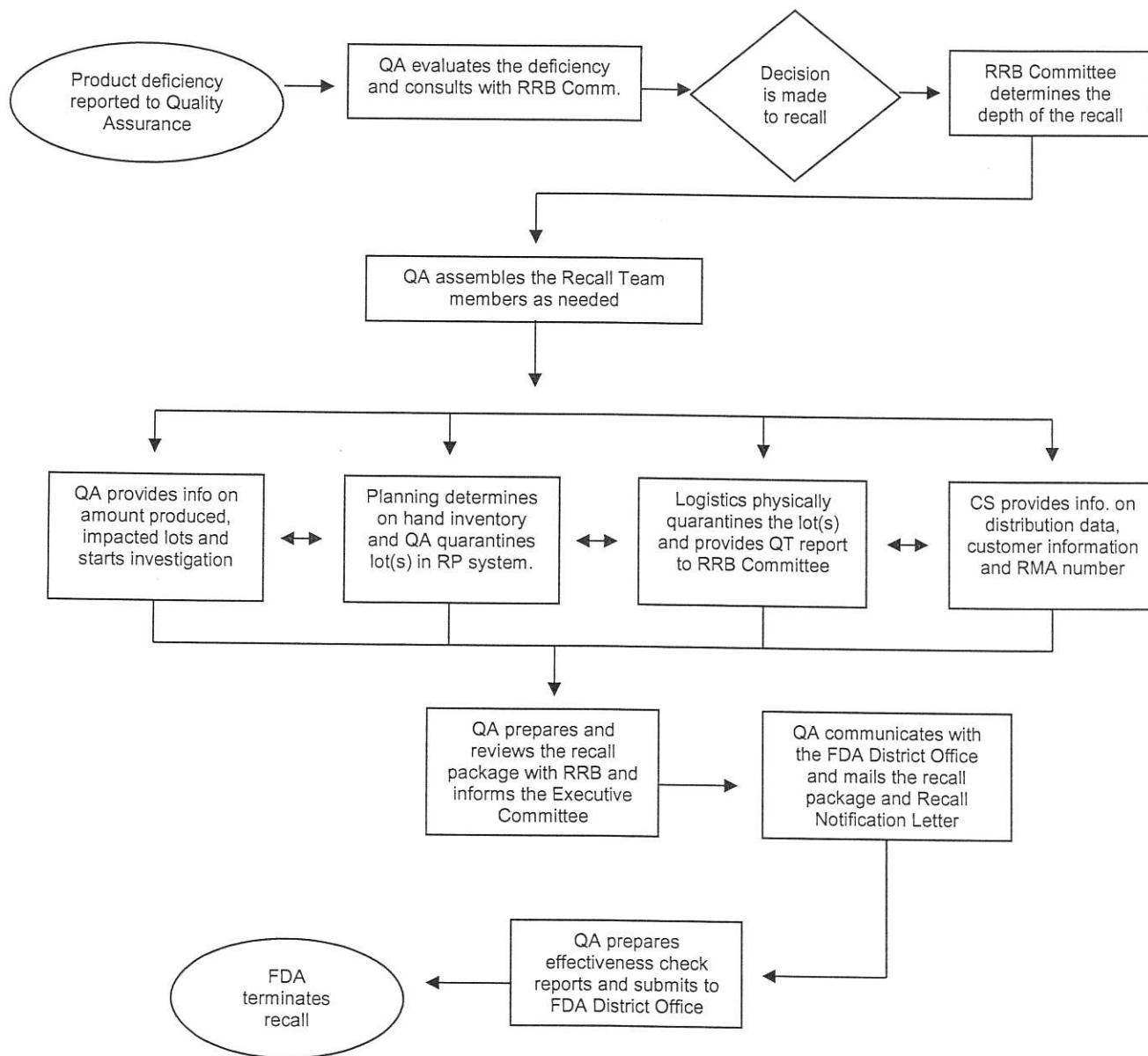
10.0 ATTACHMENTS:

10.1 Sample Recall Communication Letter

10.2 Recall Summary Report

9.1

Recall Process Flow Diagram



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10.1

Sample Recall Communication Letter

John Doe Laboratories
Somewhere, U.S.A. 12345

Control Division
Date _____

(red print) --URGENT: DRUG RECALL -- Nonsterile injectable

Re: List 1234, Cyanocobalamin Injection Lot No. 4321

Recent tests showed that the above lot number of this product is not sterile and therefore, represents a potential public health hazard. Consequently, we are recalling this lot from the market. Other lot numbers are not involved.

Please examine your stocks immediately to determine if you have any of Lot 4321 on hand. If so, discontinue dispensing the lot and promptly return via parcel post, to our New York City Plant; ATENTION RETURNED GOODS.

(NOTE: If a sub-recall is indicated in a particular situation, the following paragraph should be added:)

"If you have distributed any of lot 4321, please immediately contact your accounts, advise them of the recall situation, and have them return their outstanding recalled stocks to you. Return these stocks as indicated above."

You will be reimbursed by check or credit memo for the returned goods and postage.

Please return the enclosed card immediately providing the requested information.

This recall is being made with the knowledge of the Food and Drug Administration. The FDA has classified this recall as class _____ (if classified).

We appreciate your assistance.

John Doe
President

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Recall Summary Report (Page 1 of 4)

**Robinson Pharma, Inc.**

3330 S. Harbor Blvd., Santa Ana, CA 92704 - Phone (714)241-0235 - Fax (714)751-6066

RECALL SUMMARY REPORT**I. Recall Type**

Actual Recall ☐	Mock Recall ☐	Voluntary ☐	Involuntary ☐
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II. Recall Notice

Recall Date:	Time Initiated: Time Terminated:	Recall Initiated By:
Recall Reason: Product Contamination ☐ Misbranding ☐ Adverse Health Reaction ☐ Other ☐		
If Other, please explain:		
Robinson Pharma Head of Quality:		

III. Product(s) Being Recalled: Finished Good / Pkg. Component / RM (Circle As Applicable)

Product Code	Product Description	Lot No.	Recall Classification	Qty. Affected

IV. Provide references if product is associated with the following:

NCR #		Complaint #	
Deviation #		Other	

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Recall Summary Report (Page 2 of 4)

**Robinson Pharma, Inc.**

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V. Product Information**Manufacturing**

Lot No.	Mfg. Date	Batch Size	Qty. Produced	Expiration	Customer

Packaging

Lot No.	Pkg. Date	Batch Size	Qty. Produced	Expiration	Customer

VI. Shipping Information

Lot No.	Shipped Date	Qty. Shipped	P.O. #	Carrier Used	Destination

VII. Inventory

Lot No.	Qty. in Stock	Qty. in WIP	Qty. in Transit
			0

VIII. Customer Contact Information

Customer	Address	Telephone #	Point of Contact

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Recall Summary Report (Page 3 of 4)

**Robinson Pharma, Inc.**

3330 S. Harbor Blvd., Santa Ana, CA 92704 - Phone (714)241-0235 - Fax (714)751-6066

IX. Communication Log

Date	Time	Person Contacted	Telephone #/ Email	Remarks

X. Press Release

Agency Contacted	Date Contacted	Contact	Telephone #/ Email

XI. Returned Product

Lot No.	Date Returned	Qty. Returned	RMA #	Returned By (Carrier)

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Recall Summary Report (Page 4 of 4)

**Robinson Pharma, Inc.**

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XII. Recovery Effectiveness

Qty. Produced (A)	Qty. in Quarantine (B)	Qty. Recovered (C)	Qty. in Transit (D)	Qty. Held by Customer (E)	Qty. in Market (F)

Percentage Accountability = $(B + C + D + E + F) \div (A) \times 100$ Percentage Accountability = 100%

XIII. Recall Termination

Termination Date	Termination Time	Terminated By	Signature

*** FDA was notified of the recall termination.