Standard Operating Procedure FORM

SOP Title: Recall Initiation Form  
Document Code: FORM-VA-007  
Effective Date: 06May25  
Supersedes: [Previous Version if applicable]  
Approved By: [Name / Title]  
Review Date: [Annually or as needed]

|  |
| --- |
| ==============================================================  RECALL INITIATION FORM FORM‑VA‑007  Version: 1.0 Effective Date: 06May25  ============================================================== |
| A. RECALL HEADER  --------------------------------------------------------------  Recall ID: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date Initiated: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Initiated By (Name / Title): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Contact Phone / Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| B. PRODUCT DETAILS  --------------------------------------------------------------  Product Name / SKU: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Batch / Lot No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Pack Size: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Net Weight: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NDC No.: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Expiration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Quantity Produced: \_\_\_\_\_\_\_\_\_\_ Quantity Distributed: \_\_\_\_\_\_\_\_  Inventory On‑Hand (Warehouse): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| C. REASON FOR RECALL  --------------------------------------------------------------  □ Out‑of‑Spec COA □ Labeling Error □ Adverse Event  □ Regulatory Notice □ Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Description (brief summary of issue):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| D. RECALL CLASSIFICATION (check one)  --------------------------------------------------------------  □ Class I – Serious health risk  □ Class II – Temporary/reversible risk  □ Class III – Label/quality issue, no health risk |
| E. INITIAL ACTIONS TAKEN   | **#** | **Action** | **Responsible** | **Target Date** | **Complete (Y/N)** | | --- | --- | --- | --- | --- | | 1 | Halt distribution / block further transfers |  |  |  | | 2 | Notify internal teams (QA, Distribution, Comms) |  |  |  | | 3 | Lock inventory in BioTrack to “Recall Hold” |  |  |  | | 4 | Draft customer / dispensary notice |  |  |  | | 5 | Notify CCA per recall class timeline |  |  |  | | 6 | Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  | |
| F. RECALL TEAM CONTACTS   | **Role** | **Name** | **Phone** | **Email** | | --- | --- | --- | --- | | Recall Coordinator |  |  |  | | QA Lead |  |  |  | | Compliance |  |  |  | | Distribution |  |  |  | | Communications |  |  |  | |
| G. APPROVALS  --------------------------------------------------------------  QA Manager Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_  Compliance Director Signature: \_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_  CEO / Designee (if Class I): \_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_  ============================================================== |

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Change Description | Approved By |
|  |  | Aligned with updated Quality Manual QM-VA-001 and Master Batch Record SOP. | [Name / Title] |