

# Standard Operating Procedure FORM

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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]

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RECALL INITIATION FORM                      FORM-VA-007
Version: 1.0      Effective Date: 06May25
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<b>A. RECALL HEADER</b>
-----
Recall ID: _____
Date Initiated: _____
Initiated By (Name / Title): _____
Contact Phone / Email: _____
<b>B. PRODUCT DETAILS</b>
-----
Product Name / SKU: _____
Batch / Lot No.: _____
Pack Size: _____ Net Weight: _____
NDC No.: _____ Expiration: _____
Quantity Produced: _____ Quantity Distributed: _____
Inventory On-Hand (Warehouse): _____
<b>C. REASON FOR RECALL</b>
-----
<input type="checkbox"/> Out-of-Spec COA <input type="checkbox"/> Labeling Error <input type="checkbox"/> Adverse Event
<input type="checkbox"/> Regulatory Notice <input type="checkbox"/> Other: _____
Description (brief summary of issue):
_____
_____

<b>D. RECALL CLASSIFICATION (check one)</b> ----- <input type="checkbox"/> Class I – Serious health risk <input type="checkbox"/> Class II – Temporary/reversible risk <input type="checkbox"/> Class III – Label/quality issue, no health risk				
<b>E. INITIAL ACTIONS TAKEN</b>				
#	<b>Action</b>	<b>Responsible</b>	<b>Target Date</b>	<b>Complete (Y/N)</b>
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: _____			
<b>F. RECALL TEAM CONTACTS</b>				
	<b>Role</b>	<b>Name</b>	<b>Phone</b>	<b>Email</b>
	Recall Coordinator			
	QA Lead			
	Compliance			
	Distribution			
	Communications			
<b>G. APPROVALS</b> ----- 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	[Name / Title]

and Master Batch  
Record SOP.