1.0 Purpose

The purpose of this procedure is to define the process for the handling, investigation, and disposition of products that have been returned to Ion Labs, Inc.

2.0 Scope

This procedure applies to all products that have been manufactured/packaged, shipped, and later returned to Ion Nutritional Labs.

3.0 Responsibility

3.1 It is the responsibility of Warehouse (Shipping) personnel to follow this procedure. Warehouse employees are also responsible for immediately alerting management if a discrepancy is found upon receipt of returned product.

3.2 It is the responsibility of Quality to handle, evaluate, provide a disposition, and retain all documentation relevant to returned product.

3.3 It is the responsibility of Finance to approve all returns prior to Warehouse coordinating the return with the customer or shipping company.

4.0 Definitions

4.1 **RPAF** – Returned Product Authorization Form

4.2 **RPAN** – Returned Product Authorization Number

4.3 **RPAL** – Returned Product Authorization Log

4.4 **DC** – Document Control

4.5 **PQV** – Process Quality Verification

5.0 References

5.1 B-108, SOP, Reprocessing Procedure

5.2 C-201, SOP, Deviation and Investigation Procedure

5.3 C-502, SOP, Record Storage, Retention, and Destruction

5.4 C-501, SOP, Document Control

5.5 E-501-F1, Form, Returned Product Authorization Form

5.6 E-501-F2, Form, Returned Product Authorization Log

5.7 E-801-F1, Form, Waste Material Form

5.8 C-105, SOP, Protocol and Report Documentation Requirements

5.9 A-106, SOP, Documentation Guidelines for cGMP Records

6.0 Procedure

6.1 Authorization to Return Products

6.1.1 All return requests must be approved by Finance prior to the product being returned to the facility.

6.1.2 When a customer or shipping company calls requesting to return a product, the initiator will complete Section 1 of form E-501-F1 Return Product Authorization Form.

6.1.3 Once Section 1 is complete, form E-501-F1 Return Product Authorization Form will be submitted to Finance for approval. Once approved (Section 2), Finance will submit the form to DC to assign an RPAN.

6.1.4 DC will assign an RPAN using the following numbering format:

6.1.4.1 The letters PR for product return

6.1.4.2 Two-digit number of the year issued

6.1.4.3 Sequential three-digit number, beginning with 001

Example: PR-23-001 would be the first item returned in 2023, and was received in February.

6.1.4.4 The three digit sequential number will reset every year, beginning again at 001 for the first return of the year.

6.1.5 Once the RPAN has been assigned and logged onto form E-501-F2 Return Product Authorization Log, the form will be forwarded to Warehouse to coordinate the return and await its arrival.

6.2 Receiving Returned Product

6.2.1 Upon receipt of the returned product, Warehouse personnel must verify that the product matches the number assigned to it on the RPAF. Warehouse personnel will then complete Section 3 of E-501-F1 Return Product Authorization Form, quarantine the returned product, and identify the product as "Returned Product".

6.2.2 The product will be moved to the appropriate quarantine area until a decision has been made for final disposition.

6.2.3 Once completed, form E-501-F1 Return Product Authorization Form, the packing slip, and any other documents related to the return will be forwarded to Quality for evaluation purposes.

6.3 Evaluation of Returned Product

6.3.1 If the return is the result of a complaint, in addition to examining the integrity of the labeling and closure system, Quality will carry out a full investigation, evaluating all appropriate documentation and carrying out a visual and physical inspection and, if necessary, will request additional testing.

6.3.1.1 If additional testing has been performed, all results must be attached to E-501-F1 Return Product Authorization Form.

6.3.2 Quality will consider, among other things, the conditions under which the product has been held, stored, and shipped before or during its return, as well as the condition of the product and its packaging as a result of storage or shipping, to determine if the product's safety, identity, quality, strength, or purity has been compromised.

6.3.3 The returned product has been compromised if:

6.3.3.1 The label is damaged in a way that the identity of the product is unknown.

6.3.3.2 The container or closure system is damaged in any way (i.e. broken bottle, broken cap, or broken seal).

6.3.3.3 The product is damaged.

6.3.3.4 The product is expired.

6.3.3.5 The product does not meet visual identification.

6.3.3.6 The product fails laboratory testing (if applicable).

6.3.4 If, for any reason, the returned product has been handled in such a way that its safety, identity, or quality has been compromised, it will be rejected.

6.3.5 The reason for the return, the nature of the product, and the time elapsed since it was originally sold must also be considered during assessment.

6.3.6 Product returned for the purpose of reprocessing will be initially evaluated only for damage or loss that has occurred during transportation. Full product breakdown and inspection will not occur until the product has been staged back to Production for reprocessing. This inspection will be documented in the reprocessing protocol, as required by SOP B-108 Reprocessing Procedure.

6.3.7 Quality will complete Section 4 of E-501-F1 Return Product Authorization Form, with all of the information collected during the assessment of the product.

6.3.8 If the reason for the return implicates other batches, an appropriate investigation for the associated batches must be conducted (refer to SOP C-201 Deviation and Investigation Procedure).

6.4 Quality Review and Final Disposition of Returned Product (Section 4)

6.4.1 Returned product is to be destroyed or otherwise suitably disposed of, unless a review of the material has drawn the following disposition decisions:

6.4.1.1 The material has been approved for reprocessing (refer to SOP B-108 Reprocessing Procedure).

- If this disposition is decided, a reprocessing protocol must be generated, following SOP C-105 Protocol and Report Documentation Requirements, to control reprocessing activities. The protocol number must be referenced on E-501-F1 Return Product Authorization Form.

6.4.1.2 The product has not been damaged or compromised in any way and is acceptable for distribution in its current condition.

6.4.2 Returned product that has been rejected must be clearly labeled with a "Destroy" placard and kept in the Quarantine area until destruction.

6.4.3 Quality will document the final disposition in Section 5 of E-501-F1 Return Product Authorization Form and will forward all documentation to Finance for review.

6.4.4 Finance will complete Section 6 of E-501-F1 Return Product Authorization Form and, upon completion, will submit all associated documentation to Quality so that it may be closed and archived. Finance may retain a copy of the documentation if needed.

6.4.4.1 In the event that financial activities are the responsibility of the customer and there are no internal financial adjustments needed, Section 6 can be marked as N/A and the documents can instead be forwarded directly to Quality for closure.

6.4.5 Quality will initiate E-801-F1 Waste Material Form and will forward to warehouse for completion.

6.5 Returned Product Authorization Log (RPAL)

6.5.1 All returned products are to be logged on Form E-501-F2 Returned Product Authorization Log. This log will contain the following information:

6.5.1.1 RPAN

6.5.1.2 RPAN Issuer and date of issuance

6.5.1.3 Product Name

6.5.1.4 Customer Name

6.5.1.5 Batch Number of Returned Product

6.5.1.6 Final Disposition of Returned Product

6.5.1.7 Closed By/Date

6.6 Documentation Requirements

6.6.1 A PQV check must be performed for each completed logbook page as outlined in SOP A-106 Documentation Guidelines for cGMP Records.

6.6.2 All documents will be maintained as outlined in SOP C-501 Document Control and SOP C-502 Record Storage, Retention, and Destruction.

7.0 Revision History

Revision	Date	Description of Changes	CCR #	By
0	06/30/10	New	-	-
1	02/26/13	Changed format. Changed SOP title. Made SOP more detailed and to be in compliance with regulations.	13-058	V. Iltcheva
2	04/24/15	Biennial review. Changed format. Changed responsibilities and clarified procedure.	15-0370	V. Iltcheva
3	11/29/16	Added quality responsibility to initiate Waste Form for materials to be destroyed; added reference to E-801.0.	16-1093	E. Hasanbasic
4	03/02/20	Scheduled review: updated responsibilities.	CC-20-0153	K. Burris
5	09/19/23	Scheduled review: Updated format, added additional SOP references, changed RPAN numbering system, revised the flow of the return form to include Finance at form start, added requirements for product to be reprocessed, added document maintenance requirements, some additional minor edits made throughout.	CC-23-0473	K. Burris

ION Nutritional Labs	Return Product Authorization Form		
	Form: E-501-F1	CCR No. CC-23-0473	Revision: 5

RPAN: _____ **Issued By/Date:** _____

SECTION 1 – Returned Product Description (to be completed by Ion Representative)

Call Taken By/Date			**Complaint No (if applicable)**		
Customer Name			**Address**		
Customer Contact			**Telephone No**		
Product Name					
Packaging Size					
Dosage Form					
Batch Number		**Exp. Date**		**Total Qty**	
Reason for Return					

Return Request Taken By: _____ **Date:** _____

SECTION 2 – Finance Approval (to be completed by Finance)

Return Authorized By: _____ **Date:** _____

SECTION 3 – Receipt of Returned Product (to be completed by Warehouse)

RPAN			**Received By/Date**		
Customer Name					
Product Name					
Packaging Size					
Batch Number		**Exp. Date**		**Total Qty**	

Quarantined By: _____ **Date:** _____

RPAN: _____

SECTION 4 – Evaluation of Returned Product (to be completed by Quality)

Visual/Physical Inspection Performed		☐ **YES** ☐ **NO**	
Sample Sent to QC Laboratory for Testing		☐ **YES** ☐ **NO**	
	Number of Units		**Number of Units**
Container/Closure Intact		**Compromised**	
Labeling Intact		**Compromised**	
Other			
Comments			

Performed By: _____ **Date:** _____

SECTION 5 – Final Disposition (to be completed by Quality Management)
If reprocessing is needed, provide the protocol number in the Comments section below

Destroy	☐	**Reprocess**	☐	**Other**	☐
Comments					

Performed By: _____ **Date:** _____

SECTION 6 – Accounting Information (to be completed by Finance)

☐ N/A if financial responsibility lies with customer

Original Invoice #		**Date**		**Customer Acct #**	
Credit Memo #		**By**		**Date**	
Comments					

Performed By: _____ **Date:** _____

Closed By (Quality): _____ **Date:** _____

ION Nutritional Labs	Return Product Authorization Log		
	Form: E-501-F2	CCR No. CC-23-0473	Revision: 4

Logbook Number: _____

RPAN	RPAN Issued By/Date	Product Name	Customer Name	Batch #	Final Disposition	Entered By/Date