BODYBIO

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1.0 Purpose

1.1 To ensure that if for any reason it becomes necessary to recall any lot or batch of a BodyBio product on the market, the general procedures outlined in this standard operating procedure shall be followed.

2.0 Scope

2.1 This procedure applies to any BodyBio product that does not conform to the specifications of that product and must be removed from the market.

3.0 Responsibility

3.1 The FDA will be contacted by a BodyBio representative when a distributed product does not meet product specifications and is considered to be in violation of the law.

3.1.1 Contact Information: New Jersey District

3.1.1.1 Ruark Lanham, Recall Coordinator
900 US Customhouse, Suite 904
200 Chestnut Street, Philadelphia, PA 19106
Phone: 215-717-3738
Fax: 215-517-6649
OIIHFEast2Recalls@fda.hhs.gov

3.1.2 BodyBio Recall Coordinator

3.1.2.1 Director of Quality
45 Reese Road, Millville, NJ 08332
Phone 856-825-8335
QC@BodyBio.com

3.2 Quality Assurance (QA) will conduct mock recall and traceability exercises at least once annually to challenge the system.

4.0 References

4.1 21 CFR Part 7

5.0 Classifications

5.1 The health hazards involved will be evaluated by the FDA as follows.

5.1.1 Class I recalls as defined by 21CFR7.3(m) (1):

5.1.1.1 Class I is a situation in which there is reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.

5.1.2 Class II recalls as defined by 21CFR7.3(m)(2):

5.1.2.1 Class II is a situation in which the 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.

5.1.3 Class III recalls as defined by 21CFR7.3(m)(3):

5.1.3.1 Class III is a situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

6.0 Procedure

6.1 Quality Assurance will coordinate the following information:

6.1.1 Name of product

6.1.2 Lot number

6.1.3 Quantity of product manufactured/packaged

6.1.4 Quantity of product distributed and remaining in stock

6.1.4.1 For products manufactured prior to January 1, 2026: The **Lot Serial Transaction History** report found in **Reports** will be generated from Sage (Electronic Inventory System).

6.1.4.2 For products manufactured after January 1, 2026: The **Lot Trace Report** will be generated from NetSuite.

6.2 For products manufactured before January 1, 2026: A Quality Assurance Associate, or designee, will provide the following information by generating the **Customer Contact Traceability** report found under **Custom Reports** in Sage. For products manufactured after January 1, 2026: The **Lot Trace Report** in NetSuite will provide the following information.

6.2.1 Name and address of purchaser (phone number and email address are optional)

6.2.2 Date of purchase

6.2.3 Amount purchased and lot number

6.2.4 Other information as needed

6.3 Consignee contact by customer service

6.3.1 Class I Recall (21CFR7.3(m)(1))

6.3.1.1 Contact all customers by giving them:

6.3.1.1.1 Name of product

6.3.1.1.2 Lot number of product

6.3.1.1.3 Reason for recall

6.3.1.1.4 Shipping instructions

6.3.1.1.5 Advise retail to contact their customers

6.3.1.2 A conforming letter will be sent to all customers requesting quantities on hand. The letter shall also contain a reply letter or card with a stamped, self-addressed return envelope. All recall letters and envelopes will be stamped in red with "Urgent Product Recall".

6.3.1.2.1 **Figure 1** provides an example of the recall letter template.

6.3.1.3 All non-responses will be followed up with a second attempt.

6.3.1.4 Public warning is reserved for urgent situations deemed necessary by BodyBio's CEO, if other means appear inadequate.

6.3.1.4.1 General news media (nationally or locally) or specialized news media such as professional or trade press.

6.3.1.5 Recall effectiveness checks will be performed to verify that all consignees at the recall depth (consumer, wholesaler, retailer) have received notification and have taken appropriate action.

6.3.1.5.1 Customers will be contacted by any available source.

6.3.1.5.1.1 **Figure 2** provides an example of the recall effectiveness template.

6.3.1.5.2 Level of checks will be conducted as follows depending on the severity:

6.3.1.5.2.1 Level A: 100% of consignees

6.3.1.5.2.2 Level B: >10% < 100% of consignees

6.3.1.5.2.3 Level C: 10% of consignees

6.3.1.5.2.4 Level D: 2% of consignees

6.3.1.5.2.5 Level E- No effectiveness checks

6.3.2 Class II and III Recalls (21CFR7.3(m)(2) and (3))

6.3.2.1 Contact will be made by any available means, giving the customer:

6.3.2.1.1 Name of product

6.3.2.1.2 Lot number

6.3.2.1.3 Reason for recall

6.3.2.1.4 Shipping instructions

6.3.2.1.5 All recall letters and envelopes will be stamped in red with "Urgent Product Recall".

6.3.2.1.6 **Figure 1** provides an example of the recall letter template.

6.3.2.2 Subdistributor contact will depend on the particular facts.

6.3.2.3 Recall effectiveness checks will be performed as specified in 6.3.1.5

7.0 Disposition of Recalled Material

7.1 All recalled material, upon receipt, shall be placed in quarantine.

7.2 The reconciliation of returned material will be monitored by the Quality Team

7.2.1 Quantities specified by data processing and reply letters from distributors will be reconciled with the actual returns by the Quality Team or another designated person.

7.2.2 Any product reported and not returned or reply letters not returned will be pursued by additional correspondence.

7.3 When it is apparent that there is no product in the marketplace, the Director of Quality will take the necessary actions to close the recall.

7.4 The returned material will be reworked or destroyed depending on the particular situation. The appropriate course of action will be determined by the Director of Quality.

8.0 Mock Recall/Traceability Exercises

8.1 Mock Recall

8.1.1 The mock recall is a test to ensure that BodyBio's recall strategy is effective and adequate.

8.1.2 The QA Associate, or designee, will randomly pick a product lot (packaging components, raw material, finished product) that has been distributed into the market.

8.1.2.1 Product types should be rotated with every mock recall.

8.1.2.2 The frequency is once every year, annually.

8.1.2.3 Mock recalls shall not exceed four (4) hours.

8.1.2.4 Mock recalls will be documented using **Attachment 1**.

8.1.2.4.1 Any supporting documentation will be attached.

8.1.3 Quality Assurance will coordinate the following information:

8.1.3.1 Name of product

8.1.3.2 Lot number

8.1.3.3 Quantity of product purchased/manufactured/packaged

8.1.3.4 Quantity of product distributed and product remaining in inventory

8.1.3.4.1 For products manufactured prior to January 1, 2026: the **Lot Serial Transaction History** report found in **Reports** will be generated from Sage.

8.1.3.4.2 For products manufactured after January 1, 2026: the **Lot Trace Report** found in NetSuite will be generated.

8.1.3.5 Customers will **not** be contacted but customers contact information must be available.

8.1.3.5.1 For products manufactured before January 1, 2026: A QA Associate, or designee, will provide the customer contact information by generating the **Customer Contact Traceability** report found under **Custom Reports** in Sage.

8.1.3.5.2 For products manufactured after January 1, 2026: A QA Assocaite, or designee, will provide the customer contact information by generating the **Lot Trace Report** in NetSuite.

8.1.3.6 Examples of recall letters, postcards, and effectiveness checks will be included in the mock recall.

8.1.4 The QA Associate, or designee, will close the mock recall, and record and evaluate the effectiveness.

8.1.4.1 An effective mock recall demonstrates a 99.5%-101.5% recovery in the required time frame, taking into account normal loss, waste, or shrinkage.

8.1.4.2 If traceability is not successful, a deviation (SOP 04-026 *Planned and Unplanned Deviations*) will be initiated.

8.1.5 Reports and attachments will be filed in the QA office.

8.2 Traceability

8.2.1 This is a test to challenge our system to ensure adequate traceability.

8.2.2 Traceability exercises will be conducted at least once annually, on one finished product and one raw material, including food contact packaging components.

8.2.3 The QA Associate, or designee, will randomly pick a finished product or raw material.

8.2.3.1 Finished product lot trace exercises will involve tracing back one level and forward to the first level of distribution.

8.2.3.2 Raw material trace exercises, including food contact packaging components, will involve raw material trace-forward to all finished product in which it was used and stored.

8.2.4 Quality Assurance will coordinate the following information:

8.2.4.1 Name of product

8.2.4.2 Lot number

8.2.4.3 Quantity of product purchased/manufactured/packaged

8.2.4.4 Quantity of product distributed and remaining in stock

8.2.4.4.1 For products manufactured prior to January 1, 2026: the **Lot Serial Transaction History** report found in **Reports** will be generated from Sage.

8.2.4.4.2 For products manufactured after January 1, 2026: the **Lot Trace Report** found in NetSuite will be generated.

8.2.5 Traceability exercises will be documented using **Attachment 1**.

8.2.5.1 Any supporting documents will be attached.

8.2.6 Traceability exercises shall not exceed four (4) hours.

8.2.7 The QA Associate, or designee, will close the traceability exercise, and record and evaluate the effectiveness.

8.2.7.1 An effective traceability exercise demonstrates a 99.5%-101.5% recovery in the required time frame, taking into account normal loss, waste, or shrinkage.

8.2.7.2 If traceability is not successful, a a deviation (SOP 04-026 *Planned and Unplanned Deviations*) will be initiated.

8.2.8 Reports and attachments will be filed in the QA Office.

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Figure 1

BODYBIO

Urgent Dietary Supplement Recall

DATE

Dear Consumer/Distributor:

This letter is to inform you of a product recall involving
NAME OF PRODUCT
Lot#
Item #
UPC#
See enclosed product label

This recall has been identified due to REASON. Consumption will not cause any adverse health consequences.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall and have them return products back to you. Enclosed is a letter you should use in notifying your customers.

If determined that product is in inventory and on hand, discontinue dispensing the products and promptly return via parcel post, to our Millville, NJ Facility, ATTENTION: RETURNED GOODS.
You will be reimbursed by check or credit memo for the returned goods and postage.

This recall should be carried out to the user level.

Please complete and return enclosed response form as soon as possible.

If you have any questions, please call or email BodyBio, Inc. Customer Service.
P: 856 825 8338
E: help@bodybio.com

This recall is being made with the knowledge of the Food and Drug Administration.
We appreciate your assistance.

Brad Berman, CEO

45 Reese Road • Millville, New Jersey • 08332 • 856 825 8338
www.bodybio.com

BODYBIO

BODYBIO
Recall Return Postcard

PLEASE FILL OUT AND/OR CHECK THE APPLICABLE ITEMS AND RETURN:

☐ We do not have any stock of NAME OF PRODUCT in any of the lots listed in the BodyBio, Inc letter of DATE.
☐ We have requested our accounts to return their stocks of this merchandise to us.

We are returning _____ bottles of NAME OF PRODUCT.

Name_____
Address_____
City_____ State_____ Zip Code_____

Permit No. 2
Business Reply Mail

No Postage Stamp Necessary if mailed in U.S.A.
Postage will be paid by
BodyBio, Inc.
Millville, NJ 08332

45 Reese Road • Millville, New Jersey • 08332 • 856 825 8338
www.bodybio.com

Figure 2

BODYBIO

Date:

Dear Consumer/Distributor:

On DATE, you were notified by letter that BodyBio Inc., is recalling:

NAME OF PRODUCT
Lot#
Item #
UPC#

All products were manufactured by BodyBio Inc and distributed solely under the manufacturer's label.

Recall of the product was initiated due to **REASON** that was determined to not have any adverse health effects.

The recall notice from BodyBio, Inc. requested consumers and distributors to discontinue the use and distribution of the recalled product, as well as return all existing inventory to BodyBio, Inc. Distributors were also requested to notify their customers of the product recall, in which the customers were asked to return the product back to the distributors.

In order to advise the Food and Drug Administration about the effectiveness of this BodyBio, Inc. recall, you are requested to complete and return the enclosed questionnaire promptly using the prepaid self-addressed envelope.

If you have any questions or problems with this request, Please call or email:

BodyBio, Inc.,
Customer service
P: 856 825 8338
E: help@bodybio.com

Thank you for your cooperation,

Brad Berman, CEO

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www.bodybio.com

BODYBIO

Product Recall

PLEASE READ EACH QUESTION AND CHECK THE PROPER ANSWER YOU HAVE CHOSEN. PLEASE CHECK WITH ANYONE WHO MAY HAVE RECEIVED THIS NOTIFICATION BEFORE ANSWERING.

Date _____

1. Did you, the consumer or distributor, receive notification that BodyBio, Inc. is recalling its **NAME** product?
   YES_____ NO_____
2. Did you, the consumer or distributor, receive shipments of the product being recalled?
   YES_____ NO_____
3. Do you now have any of the recalled product on hand? (Please check inventories before answering)
   YES_____ NO_____
4. If the answer to question 3 is YES, do you intend to return the product to the BodyBio, Inc. as requested?
   YES_____ NO_____
5. If the answer to question 4 is NO, please explain your intentions

_____

Name of person completing questionnaire:

_____

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Revision History

Revision	Comment
0	New
1	Removed President (John)
2	Changed Title from "Procedure" to "Strategy" Added FDA to Responsibility Deleted bodybio personnel recommendations Added FDA contact information
3	Designated recall coordinator (Sarah) Added mock recall procedure
4	Changed mock recall frequency from biennially to annually.
5	Updated Format and Fixed number values. Updated Recall Coordinators Added Sage (Electronic Inventory System) to Procedure Changed the frequency of Mock recall from annually to twice a year. CEO changed to President
6	Fixed format. Added frequency of mock recall and traceability. Added NSF GMP requirements as a reference. Added specific names of SAGE reports. Removed Systems Project Manager from the procedure. Added Figure 1 as an example of the recall urgent letter and response card. Added figure 2 as an example of the recall effectiveness check letter. Changed President title to CEO. Added more specific details to mock recall. Added traceability exercise procedure. Added attachment 1 to document mock recall and traceability.
7	Fixed spelling, grammatical and formatting errors throught the document. Changed 3.1.2 BodyBio Recall Coordinator to any Quality Control Designee. Changed Mock Recall schedule to once annually. Added Change control Numebr to Revsion History.
8	Updated traceability to once annually.
9	• Updated FDA contact information. • Added process for recalls/traceability in NetSuite throughout document. • Updated grammar throughout. • Updated header with new logo and removed prepared and approved by signatures and effective date/supersedes • Removed date and change control number from revision history

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BodyBio Inc

Request For Document Action

Doc. Name: Recall Strategy

Doc. Code: BBI-QA/QC–003

Publish Date: 05/06/2026

Document Info

Doc. Code: BBI-QA/QC–003 **Doc. Ref:** SOP 01-003

Document Name:	Recall Strategy		
Doc Description:			
Document Type:	SOP	**Department:**	Quality
Document Owner:		**Document Category:**	

Revision Info

Requestor:	Alexandra Dittus	**Resp. Party:**	Alexandra Dittus	**Status:**	Active
Previous Revision:	8	**Current Revision:**	9	**Document Location:**	QT9
Document Author:		**Physical Location:**			

Description of change to document

☐ Training Required

•Updated FDA contact information to add correct email address.
•Added process for recalls/traceability in NetSuite throughout document to include process for new ERP system.
•Updated grammar throughout for correctness.
•Updated header with new logo and removed prepared and approved by signatures and effective date/supersedes - for consistency and format for QT9
•Removed date and change control number from revision history - format for QT9

Comments

Entry Date	Author	Entry

Collaboration

Collab User	Status	Date Completed	Notes

Affected Departments

Dept Code	Department	Inactive
QA/QC	Quality	☐

Affected Documents

Doc. Code	Name	Department	Doc. Type	Site	Relation
BBI-QA/QC–003	Mock Recall-Traceability Exercise Report	Quality	Form	BodyBio Inc	Child Of

Approvals

Approvers

Approver	Approved	Date Approved
John Kim	☑	04/08/2026

BodyBio Inc

Request For Document Action

Doc. Name: Recall Strategy

Doc. Code: BBI-QA/QC–003

Publish Date: 05/06/2026

Approver	Approved	Date Approved
Jignesh Soni	☑	04/08/2026

Approval Notes

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05/06/2026 12:15:40 PM -04:00	Alexandra Dittus	Approved from new document queue
04/08/2026 3:39:37 PM -04:00	Jignesh Soni	Document Approved With the following notes: Approved
04/08/2026 3:30:26 PM -04:00	John Kim	Document Approved With the following notes: approved

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Related Files

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Recall Strategy - redline.DOCX

Affected Products

Product Name	Part Number	Description	Inactive