BODYBIO

| SOP# 01-003.8 | Standard Operating Procedure | Written By/Date: 01/04/24 |
|---|---|---|
| Effective Date JAN 04 2024 | **Recall Strategy** | Approved By/Date: 01/04/2024 |
| Supercedes 11/09/23 | | Page 1 of 11 |

## 1.0 Purpose

1.1 To ensure that if for any reason it becomes necessary to recall any lot or batch of BodyBio's 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 product of BodyBio's that does not conform to the specifications of that product and must be removed from the market.

## 3.0 Responsibility and Frequency

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
orahafeast2recalls@fda.hhs.gov

3.1.2 BodyBio Recall Coordinator

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

3.2 Mock recall and traceability exercises will be conducted at least once annually to challenge the system.

## 4.0 References

4.1 21 CFR 7.3

4.2 NSF GMP Requirements

## 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 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 Control and/or Manufacturing will coordinate the following information:

6.1.1 Name of product

6.1.2 Lot Number

6.1.3 Quantity of product manufactured/packaged

6.1.3.1 Receiving records and/or batch folders.

6.1.4 Quantity of Product Distributed

6.1.4.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

6.1.5 Quantity of product remaining in stock

6.1.5.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

6.2 Customer service or designee will provide the following information by pulling the **Customer Contact Traceability** report found under **Custom Reports** from Sage (Electronic Inventory System).

6.2.1 Name, phone number and address of purchaser

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 telephone 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 template.

6.3.1.3 All non-responses will be followed up with telephone calls, e-mail, or a second mailing.

6.3.1.4 Public warning is reserved for urgent situations deemed necessary by the President 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 Contact will be made by e-mail, telephone, mail, or combination.

6.3.1.5.1.1 Figure 2 provides an example of the 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 mail, e-mail, telephone, or a combination giving them:

6.3.2.1.1 Name of product

6.3.2.1.2 NumberLot 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".

6.3.2.1.5.1 Figure 1 provides an example of the 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 recall material upon receipt shall be placed in quarantine.

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

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

7.2.2 Any product reported and not returned or reply letters not returned will be pursued by more telephone, e-mail, or mail correspondence.

7.3 When it is apparent that there is no product in the marketplace, the President 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 CEO.

## 8.0 Mock Recall/Traceability Exercises

8.1 Mock Recall

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

8.1.2 The recall coordinator 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 Control and/or Manufacturing 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

8.1.3.3.1 Receiving records and/or batch folders

8.1.3.4 Quantity of Product Distributed

8.1.3.4.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

8.1.3.5 Quantity of product remaining in stock

8.1.3.5.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

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

8.1.3.6.1 Customer service or designee will provide the following information by pulling the **Customer Contact Traceability** report found under **Custom Reports** from Sage (Electronic Inventory System).

8.1.3.7 Examples of recall letters, postcards, and effectiveness checks are mentioned in this recall strategy.

8.1.4 The Recall coordinator 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 Failure Investigation/CAPA (SOP 04-009 Attachment 1) will be opened.

8.1.5 Reports and attachments will be filed in the Quality Control lab.

8.1.6 Reports will be distributed to Senior management and all involved.

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 recall coordinator 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 Control and/or Manufacturing 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

8.2.4.3.1 Receiving records and/or batch folders

8.2.4.4 Quantity of Product Distributed

8.2.4.4.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

8.2.4.5 Quantity of product remaining in stock

8.2.4.5.1 **Lot Serial Transaction History** report found in **Reports** will be pulled from Sage (Electronic Inventory System).

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 recall coordinator will close the traceability exercise, and record and evaluate the effectiveness.

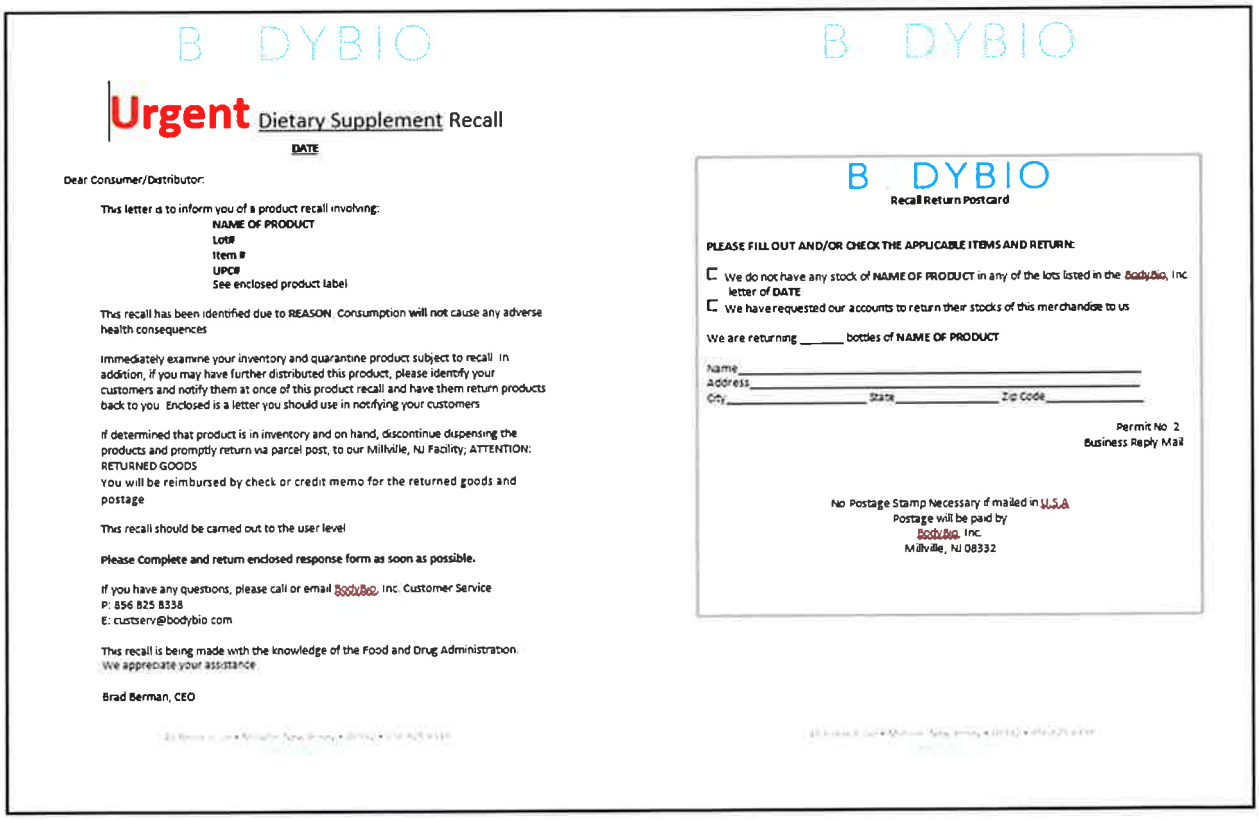
8.2.7.1 An effective traceability exercise demonstrates a 99.5%-101.5% recovery in the required time frame, taking into account normal loss, waste, or shrinkage.

8.2.7.2 If traceability is not successful, a Failure Investigation/CAPA (SOP 04-009 Attachment 1) will be opened.

8.2.8 Reports and attachments will be filed in the Quality Control lab.

8.2.9 Reports will be distributed to Senior management and all involved.

## 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: custserv@bodybio.com

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

Brad Berman, CEO

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

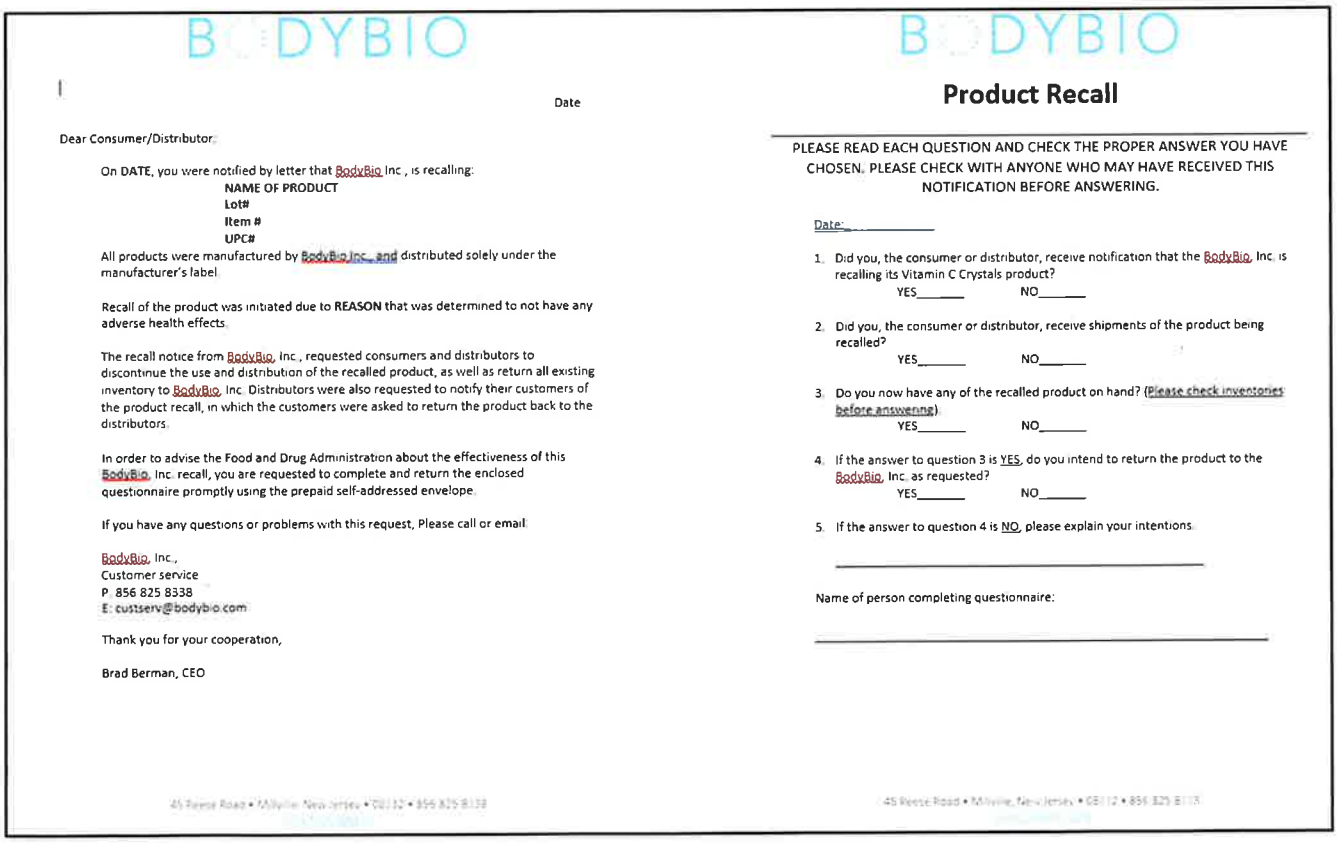
We are returning _____ bottles of NAME OF PRODUCT

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

# Figure 2



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: custserv@bodybio.com

Thank you for your cooperation,

Brad Berman, CEO

45 Reese Road • Millville, New Jersey • 08332 • 856 825 8338

## 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 the BodyBio, Inc. is recalling its Vitamin C Crystals 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:

_____

45 Reese Road • Millville, New Jersey • 08332 • 856 825 8338

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## Revision History

| Date | Chance Control # | Revision | Comment |
|---|---|---|---|
| 4-9-10 | | 0 | New |
| 4-5-11 | | 1 | Removed President (John) |
| 10-30-13 | | 2 | Changed Title from "Procedure" to "Strategy"<br>Added FDA to Responsibility<br>Deleted bodybio personnel recommendations<br>Added FDA contact information |
| 2-9-16 | | 3 | Designated recall coordinator (Sarah)<br>Added mock recall procedure |
| 3-17-16 | | 4 | Changed mock recall frequency from biennially to annually. |
| 01-23-19 | | 5 | Updated Format and Fixed number values.<br>Updated Recall Coordinators<br>Added Sage (Electronic Inventory System) to Procedure<br>Changed the frequency of Mock recall from annually to twice a year.<br>CEO changed to President |
| 11-26-19 | | 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. |
| 11-09-23 | 2318 | 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. |
| JAN 04 2024 | 2377 | 8 | Updated traceability to once annually. |