SOP COVER PAGE

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EFFECTIVE DATE:	12/19/2022	SUPERSEDES VERSION:	GP-006 Release 4

If the SOP is reviewed and there are no changes (i.e. if it is not revised) then a signature and date (below) indicate the review has occurred. If a revision is required, a new version is released and the signature/date (below) does not need to be completed.

Review Date:		Signature:
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Review Date:		Signature:

Approval of this page indicates approval of all pages in this procedure.

1. PURPOSE

1.1. This Standard Operating Procedure (SOP) establishes recall and withdrawal procedures for MBi Nutraceuticals products that are found to not meet minimum standards for quality and safety.

2. SCOPE

2.1. This SOP applies when MBi Nutraceuticals recalls its products from the marketplace for any reason, including product mislabeling, potential health hazards from contaminated finished products, raw materials, packaging, or suppliers, or if the product has caused a foodborne illness outbreak.

3. RESPONSIBILITIES

3.1. MBi President

3.1.1. Fulfills role as a recall team member, available for 24/7 contact in case of recall procedure, and rehearses at least twice yearly for mock recall exercises.

3.1.2. Gives final approval to recall products which meet the criteria outlined in this SOP

3.1.3. Seeks legal and expert advice

3.1.4. Provides input for developing, revising, and maintaining this SOP

3.2. VP of Business Development

3.2.1. Fulfills role as a recall team member, available for 24/7 contact in case of recall procedure, and rehearses at least twice yearly for mock recall exercises.

3.2.2. Notifies direct consignees of product being recalled and gives instructions for returning or disposing of recalled products.

3.2.3. Follows up to check effectiveness of consignee communication to recover or destroy recalled products.

3.2.4. Communicates with the media and issues press releases, if necessary.

3.2.5. Provides input for developing, revising, and maintaining this SOP.

3.3. Quality Assurance Manager

3.3.1. Fulfills role as a recall team member, available for 24/7 contact in case of recall procedure, and rehearses at least twice yearly for mock recall exercises.

3.3.2. Contacts and acts as an intermediary with regulatory agencies.

3.3.3. Conducts investigation to find root cause of issue leading to recall.

3.3.4. Develops, revises, and maintains this SOP, keeping references and contact information current.

3.4. Quality Control Manager

3.4.1. Fulfills role as a recall team member, available for 24/7 contact in case of recall procedure, and rehearses at least twice yearly for mock recall exercises.

3.4.2. Collects data to assess safety and quality issues that will determine the depth and scope of a recall.

3.4.3. Provides input for developing, revising, and maintaining this SOP.

3.5. Customer Service Manager

3.5.1. Fulfills role as recall team leader, available for 24/7 contact in case of recall procedure, and rehearses at least twice yearly for mock recall exercises.

3.5.2. Compiles pertinent information for the recall plan, such as product information, consignee contact information, data, and response details.

3.5.3. Fields all recall-related correspondence, such as emails, posted mail, phone calls, and in-person visits.

3.5.4. Monitors recall progress and assists team members to ensure that the recall completion time frame is on schedule.

3.5.5. Provides input for developing, revising, and maintaining this SOP.

3.6. VP of Operations

3.6.1. Acts as a back-up recall team member, fulfilling the role of any team member who is unavailable or unable to perform their duties for the recall procedure. Rehearses at least twice yearly for mock recall exercises.

3.6.2. When fulfilling the role as a recall team member, is available for 24/7 contact.

4. REFERENCES

4.1. U.S. Food and Drug Administration, 21 CFR 7

4.2. U.S. Food and Drug Administration, Industry Guidance for Recalls, Information on Recalls of FDA Regulated Products: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls

4.3. U.S. Food and Drug Administration, Regulatory Procedures Manual, March 2010, Chapter 7 Recall Procedures: https://www.fda.gov/media/71814/download

4.4. Health Canada and RQC, Recall Policy for Health Products https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/recall-policy-0016/policy.html

pasteur@rqcpartners.com +1-416-613-7775

4.5. SOP QC-031 Deviations and CAPAs

5. CONTACT INFORMATION

5.1. U.S. Food and Drug Administration, Division of Human and Animal Food Operations West IV

Building 20, Denver Federal Center

Phone: 303-236-3045

Email: orahafwest4recalls@fda.hhs.gov

5.2. Health Canada and RQC Partners

Health Canada Regulatory Operations and Enforcement Branch phone: 1-800-267-9675

Email for drugs and natural health products: hc.hpce-cpsal.sc@canada.ca

RQC Compliance phone: 1-416-613-7775

RQC Email: pasteur@rqcpartners.com

5.3. NSF International

Regulatory Affairs Hotline: 1-800-673-8010

Email: regulatory@nsf.org

5.4. Associated Press

Salt Lake City, Utah Bureau

Phone: 801-322-3405

6. RECALL CLASSIFICATIONS

6.1. The FDA classifies recalls into numerical designations (I, II, or III) to indicate the relative degree of health hazard presented by the product being recalled:

6.1.1. Class I - dangerous or defective products that have reasonable probability of causing serious health problems or death. Examples include but are not limited to the following:

6.1.1.1. Pathogens: Salmonella, Listeria monocytogenes, E. coli O157:H7, Clostridium

6.1.1.2. Undeclared allergens: milk, eggs, peanuts, tree nuts, crustaceans, fish, soybeans

6.1.1.3. High levels of sulfites

6.1.1.4. High levels of heavy metals

6.1.1.5. Choking hazards for susceptible populations

6.1.2. Class II - products have reasonable probability of causing temporary or medically reversible adverse health consequences or remote probability of serious adverse health consequences. Examples include, but are not limited to the following:

6.1.2.1. Foreign objects that pose a physical hazard

6.1.2.2. Pathogens: Shigella, hepatitis A, Cyclospora, Cryptosporidium

6.1.2.3. Undeclared allergen: wheat

6.1.3. Class III - product is not likely to cause adverse health consequences, but violates FDA labeling or manufacturing regulations. Examples include, but are not limited to the following:

6.1.3.1. Container defects (plastic material delamination or a lid that does not seal).

6.1.3.2. Off taste, color, or leaks

6.1.3.3. Low levels of pesticide residue

7. PROCEDURE

7.1. A product recall may be initiated for reasons including, but not limited to any of the following:

7.1.1. A regulatory agency has mandated a recall as a result of a violation of a government act, standard, or other mandatory regulation.

7.1.2. To avoid potentially serious product liability claims or losses.

7.1.3. Field monitoring reports, feedback, or consumer complaints indicate that product tampering may have taken place.

7.1.4. Additional research and product testing suggests the necessity of a recall.

7.1.5. Characteristics of the product are found to not match advertised claims for safety or effectiveness.

7.2. Regulatory body notification

7.2.1. Once MBi Nutraceuticals management has confirmed the need for a recall, the FDA should be notified in a timely manner (see section 5.1 for contact information). Health Canada, Canadian Importer or other applicable agencies may need to be contacted, depending on the region of product distribution.

7.2.2. Recall procedures may vary by regulatory agency. See references in section 4 for applicable industry guidance resources.

7.2.3. NSF International should also be contacted, according to MBi Nutraceuticals' NSF certification agreement (see section 5.3 for contact information).

7.2.4. Information needed by the FDA should be readily available in product manufacturing and distribution records and includes:

7.2.4.1. Product identity, size and container type, brand names, lot numbers, whether refrigerated/frozen/shelf stable

7.2.4.2. Codes

7.2.4.3. Amount manufactured and distributed

7.2.4.4. List of consignees

7.2.4.5. Area of distribution

7.2.4.6. Reason for recall and hazard involved

7.2.4.7. Actual labels or clear photos of labels

7.3. The depth of the recall is generally determined by the classification designation of the recalled product (described in section 6).

7.3.1. In Class I recalls, efforts should be made to recall each product to the consumer/user level. All retailers and wholesalers should be contacted and instructed on the disposition of the product (see section 7.4). A press release should be issued to notify as many affected consumers/users as possible (see section 7.5).

7.3.2. In Class II recalls, efforts should be made to recall products to the retail level (see section 7.4). Consumers/users may also be notified via press release (see section 7.5).

7.3.3. In Class III recalls, efforts should be made to recall products to the retail level (see section 7.4). Whether the defect will be obvious to the consumer should be assessed when deciding to notify by press release or other measures (see section 7.5).

7.4. Consignees should be notified by phone and letter or email. Copies of letters and emails should be retained for documentation. If a consignee is contacted by phone, a letter or email should also be sent to document the communication. When possible, the text of phone conversations should be retained for documentation.

7.4.1. The FDA's Model Letter Exhibits 7-4 Recall letter, 7-5 Recall Return Response Form, and 7-6 Recall Envelope (found under the reference in section 4.2) should be used as templates for communicating with consignees. Consignees should be instructed how to return or dispose of the affected product.

7.4.2. FDA Model Letter Exhibits 7-1 Effectiveness Check Letter, and 7-2 Effectiveness Check Response Format (found under the reference in section 4.2) should be used as templates for followup communication after giving initial recall instructions to consignees. This letter and

form can be used in conjunction with Model Letter Exhibit 7-3 Effectiveness Check Questionnaire, which can be used as a script when calling consignees on the phone.

7.4.3. Consignees who do not respond to communication described in 7.4.1 and 7.4.2 should be recontacted until recall instructions can be given and effectiveness checks conducted.

7.5. Media communications

7.5.1. Use one of the FDA's Index of Model Press Releases as a template and follow as closely as possible. Model Press Releases can be found under the reference in section 4.2.

7.5.2. Do not change the hazard statement. For example, do not take out "life threatening", if the product is potentially life threatening.

7.5.3. MBi may request their FDA Division's review of press releases before they are issued to prevent misunderstandings between MBi, its customers, and the FDA

7.5.4. Issue the press release to Associated Press (see section 5 for local bureau phone contact information).

7.5.5. Provide the FDA and other applicable agencies with confirmation that the press release was sent to AP. The FDA will issue a press release if MBi takes too long or if the FDA determines that MBi's statement is inadequate.

7.6. Data collection and investigation to determine the root cause of a withdrawal or recall

7.6.1. Testing should be performed to determine if the issue only exists in one product lot or if a raw material or component present in multiple finished product lots may necessitate increasing the scope of the recall.

7.6.2. Environmental contamination of the facility may also affect multiple products and the scope of the recall.

7.6.3. If necessary, a third party laboratory or other experts should be consulted with to obtain data that MBi does not have instrumentation or methods to acquire or to confirm results.

7.6.4. Details of the investigation and action taken should be documented.

7.7. Recall termination (see reference in section 4.1, 21 CFR 7.55).

7.7.1. A recall may be terminated when the following criteria are met:

7.7.1.1. All reasonable efforts have been made to remove or correct the product in accordance with the recall strategy.

7.7.1.2. It is reasonable to assume that the product has been removed and properly disposed or corrected according to the degree of hazard of the recalled product.

7.7.2. When the FDA determines that criteria for terminating the recall are met, MBi will receive written notification from the appropriate FDA district office

7.7.3. MBi may request termination of its recall by submitting a written request to the appropriate FDA district office, stating that the recall is effective in accordance with the criteria in section 7.7.1, and accompanying the request with the most current recall status report and a description of the disposition of the recalled product.

7.8. Follow-up actions

7.8.1. Data and documentation from the recall should be reviewed and corrective/preventive actions (CAPAs) should be implemented and completed (see SOP QC-031, Deviations and CAPAs). Examples of possible CAPAs include, but are not limited to the following:

7.8.1.1. Product redesign

7.8.1.2. SOP modification

7.8.1.3. Process validation

7.8.1.4. Employee training

7.8.1.5. Increased process monitoring

7.8.2. All corrective actions should be qualified/validated.

7.8.3. Responsibility should be assigned to make sure that corrective actions are implemented and satisfactorily completed.

7.8.4. Nonconformance information must be provided to those responsible for the areas in which the nonconformance occurred.

7.9. Mock recall exercises should be conducted at least twice annually to review withdrawal and recall system effectiveness.

8. RECORDS, REPORTS, AND FORMS

8.1. Records shall be retained as required for the recall procedure by the appropriate regulatory agency.

8.2. Recall Report

8.3. Recall Status Reports

8.4. Deviation/CAPA log

8.5. Deviation Reports

9. HISTORY

Release No.	Effective Date	Reason/Justification for Change
1	08/01/05	New
2	10/18/10	Updated SOP format including cover page, release history. Added sections to conform with SOP template section headings. Added additional FDA and HC recall guide references. Included potential reasons for a recall. Moved example of FDA recall instructions to Appendix A.
3	08/27/19	Updated personnel. Reformatted. Removed Appendix A, and cited FDA recall instructions in the references.
4	01/31/2020	Added recall classifications, FDA and other agency contact information. Updated recall team responsibilities, references, FDA contacts. Created a recall report form and Appendix with 24 hour recall team member contact information.
5	12/16/2022	Added RQC Partners contact information for Canada. Updated team.

APPENDIX A

RECALL TEAM MEMBER 24 HOUR CONTACT INFORMATION

Recall Team Member Role	**Name**	**Phone Number**
MBi Owner/President	Ned Jensen	801-376-2655
Recall Team Leader	Michelle Jensen	801-360-7993
Public Relations Coordinator	Jeff Jensen	801-361-7740
Regulatory Agency Intermediary	Kim Griffin	801-822-1666
Data Collection	Carson Burnside	817-915-9937
Backup Team Member	Trent Jensen	801-472-8854

RECALL REPORT (COPY)

PRODUCT UNDER RECALL INFORMATION:

CODE: _____ BRAND NAME(S): _____

LOT NUMBER(S):_____ SIZE(S):_____

CONTAINER TYPE(S): _____ STORAGE CONDITION: _____

RECALL APPROVED BY (PRINT): _____

SIGNATURE:_____ DATE: _____

RECALL TERMINATION DATE: _____

RECALL TEAM MEMBER INFORMATION:

MBi Owner/President: _____ Phone: _____

Recall Leader: _____ Phone: _____

PR Coordinator: _____ Phone: _____

Regulatory Agency Intermediary: _____ Phone: _____

Data Collection: _____ Phone: _____

Backup Team Member: _____ Phone: _____

REGULATORY AGENCIES, LEGAL COUNCIL, EXPERTS CONTACTED:

Regulatory Agencies Contacted: _____

Legal Council Contacted: _____

Outside Experts Contacted: _____

Media Outlets Contacted: _____

NONCONFORMANCE QUESTIONNAIRE:

1. Description of nonconformance: _____
2. How was the nonconformance identified (e.g. complaint, in-house data, etc)? _____
3. Has the nonconformance resulted in injury or death? _____
4. What is the FDA recall classification (see SOP GP-006, Product Recall, section 6)? _____

The following questions apply if a component or raw material, at least partly, caused the defect:

5. Was the same component used in other products manufactured by MBi? _____
6. Has MBi conducted analysis to assure that the component or raw material doesn't have deleterious effects on other products? _____
7. Has the component or raw material manufacturer been contacted? _____
8. If answer to #6 is yes, has the component or raw material manufacturer contacted its other customers about the problem? _____
9. Was the component or raw material sampled and tested for the defect before use in the finished product? _____
10. If answer to #8 is no, why not? _____

The following questions apply if the product label was inaccurate, or the wrong label was applied (label mix-up):

11. What quality system procedures should have been established to prevent the problem? _____

_____

12. If the label or instructions for use were inaccurate, was the inaccuracy introduced in the design stage, or was it due to a printing problem? _____

The following questions apply if the product has been on the market for a year or more:

13. Why was the problem not detected earlier? _____
14. Was the procedure for determining if a recall is necessary followed? _____
15. Were other causes for the problem explored? _____
16. If the problem was introduced via a formulation change, were established change control procedures followed? _____
17. If answer to #15 is yes, are the change control procedures adequate? _____
18. Was the nature of the problem such that it should have been anticipated, and the design verification/ validation study fashioned to detect the problem? _____
19. Have all products been recalled which were distributed since the formulation change was introduced? If not, why not? _____

ATTACH THE FOLLOWING DOCUMENTATION:

- ❑ Complete product manufacturing and distribution records
- ❑ Actual labels or clear photos of labels
- ❑ Applicable Laboratory Reports, log entries
- ❑ Copies of all letters and/or emails sent to and received from consignees
- ❑ Transcripts of phone conversations with consignees
- ❑ Copies of all correspondence with the FDA or other applicable regulatory agencies
- ❑ Copies of press releases and confirmation of press release submission
- ❑ Deviation Reports
- ❑ Copies of all Recall Status Reports

RECALL STATUS REPORT (COPY)

Recall Status Reports should be completed and submitted to the appropriate FDA district office every 2 to 4 weeks, depending on the urgency of the recall. This page may be copied as many times as necessary to create up to date recall status reports until the recall is terminated. The table below may be modified to include all consignees, or additional pages may be attached.

CONSIGNEES NOTIFIED OF THE RECALL:

#	Name	Date notified	Method of notification	Response received? (Y/N)	Quantity of products on hand at time of notification	Number of Products returned or corrected	Effectiveness check results
1							
2							
3							
4							

Number of products returned or corrected: _____

Quantity of products accounted for: _____

Estimated time frame for recall completion: _____

Recall Status Report completed by (Print): _____

Signature: _____ Date: _____