

Form Approved: OMB No. _____

Expiration Date: _____

See OMB Statement on inside cover

SURVEY OF
MANUFACTURING PRACTICES
IN THE
DIETARY SUPPLEMENT INDUSTRY

Final

October 26, 1999

Research Triangle Institute
Center for Economics Research
Research Triangle Park, NC 27709

Public reporting burden for this collection of information is estimated to average 1.13 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing this burden to:

Peter Vardon
U.S. Department of Health and Human Services
Food and Drug Administration
330 C Street, SW
Washington, DC 20204

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Introduction

The Research Triangle Institute (RTI) is conducting a survey of the dietary supplement industry as part of a research study for the U.S. Food and Drug Administration (FDA). The purpose of this survey is to learn about the existing manufacturing practices in the industry. This effort is part of the process of considering whether to institute rulemaking to require good manufacturing practice (GMP) regulations for the dietary supplement industry.

This plant was randomly selected to participate in this survey. Please answer all questions as they pertain to the plant named on the mailing label attached to the front of this survey booklet. ***Plant is defined as all of the buildings and facilities, including warehouses, used in your dietary supplement operations and within the general area of the address shown on the mailing label.***

Your participation is voluntary, and your responses will be kept strictly **confidential**. Only anonymous data (no identifying information on your plant) will be provided to the FDA. Only aggregate results will be reported to the public.

The survey will take about an hour to complete. Please answer each question by circling the appropriate answer(s) or writing your answer in the space provided. For the purposes of this survey, RTI has defined many of the terms used in the survey. These definitions are provided in the left margin. ***Please return the completed survey in the enclosed postage-paid return envelope within five business days.***

If you have any questions on this research study, please contact:

Peter Vardon
U.S. Department of Health and
Human Services
Food and Drug Administration
330 C Street, SW
Washington, DC 20204
Phone: 202-205-5329
e-mail: PVardon@bangate.fda.gov

or **Heather Carter-Young**
Center for Economics Research
Research Triangle Institute
P.O. Box 12194
Research Triangle Park, NC 27709-2194
Phone: 1-800-334-8571 (ext. 8331)
e-mail: cyoung@rti.org

If you have questions regarding your rights as a research participant, you may contact Dr. Steven Garfinkel at RTI (1-800-334-8571 ext. 6382).

Questions?

Call the Survey Helpline (1-800-866-7655, ext. 548)

If you have any questions as you complete the survey, please call the Survey Helpline at 1-800-866-7655 and ask for Michele LaPrade, extension 548. The Helpline is operated by Harris Interactive, on behalf of RTI, and operates on weekdays from 8:00 a.m. to 5:00 p.m. EST.

1

Products and Markets

1.1 Which of the following describes the dietary supplement operations at this plant? (*Circle all that apply.*)

1. Manufacturer—manufacture dietary supplements from ingredients, may package and label the product itself or transfer it to a repackager/relabeler/encapsulator or distributor
2. Repackager/relabeler/encapsulator—repackage, relabel, or encapsulate dietary supplements manufactured by another firm
3. Ingredient or input supplier—supply ingredients or bulk finished products used to manufacture dietary supplements at this plant or another firm
4. Distributor—distribute products manufactured by this plant or another firm
5. Importer—import either ingredients for further processing or finished products for distribution
6. Exporter—export either ingredients for further processing or finished products for distribution
7. Other (*Specify*): _____

1.2 For your dietary supplement operations at this plant, what is the product type for your **primary line of business**? (*Circle only one.*)

(Your plant's primary line of business for your dietary supplement operations is defined as the one that contributes the majority of revenues—either greater than 50% of revenues or the greatest of several lines such as 35% if all other lines contribute less.)

1. Vitamins and minerals
2. Herbals and botanicals, not including extracts
3. Herbal and botanical extracts
4. Amino acids
5. Protein products
6. Animal extracts
7. Concentrates, metabolites, and constituents
8. Other (*Specify*): _____

1.3 What **other** product types, not including your primary line of business, **do you produce** at this plant? By produce we mean, manufacture, repack/relabel/encapsulate, supply ingredients, distribute, import, or export. (*Circle all that apply.*)

1. Vitamins and minerals
2. Herbals and botanicals, not including extracts
3. Herbal and botanical extracts
4. Amino acids
5. Protein products
6. Animal extracts
7. Concentrates, metabolites, and constituents
8. Other (*Specify*): _____

1.4 Does this plant produce any food products other than dietary supplements?

1. Yes
2. No

1.5 Does this plant produce any over-the-counter (OTC) or prescription (Rx) drugs? (*Circle only one.*)

1. Yes, OTC drugs
2. Yes, Rx drugs
3. Yes, OTC and Rx drugs
4. No

1.6 Is this plant a member of any of the following trade organizations? (*Circle all that apply.*)

1. American Herbal Products Association (AHPA)
2. Consumer Health Products Association (CHPA) (formerly known as Nonprescription Drug Manufacturers Association)
3. Council for Responsible Nutrition (CRN)
4. National Nutritional Foods Association (NNFA)
5. Utah Natural Products Alliance (UNPA)
6. Other (*Specify*): _____

2 Good Manufacturing Practices (GMPs)

For the purposes of this survey, **Good Manufacturing Practices (GMPs)** are the minimum sanitary and processing procedures that a company may have written, adopted, or may follow in practice to ensure that dietary supplements are of consistent quality and contain no unintended components (for example, contaminants) that may pose a safety concern or are otherwise necessary to ensure that a product is not adulterated.

2.1 Does this plant follow a published **Good Manufacturing Practices (GMPs)** model for the dietary supplement products produced at this plant?

1. Yes
2. No Skip to question 2.3

2.2 Which of the following are your GMPs for dietary supplement operations patterned after? *(Circle all that apply.)*

1. FDA Food CGMPs (21 CFR Part 110)
2. Advance Notice of Proposed Rulemaking for Dietary Supplements
3. National Nutritional Foods Association (NNFA) GMPs
4. FDA Drug CGMPs (21 CFR Parts 210 and 211)
5. U.S. Pharmacopeia (USP) GMPs
6. Other *(Specify):* _____

Skip to question 2.5

2.3 If **not** following published GMPs, how does this plant verify the identity, purity, and composition of dietary supplement products and ingredients? *(Circle all that apply.)*

1. Sanitation standard operating procedures (SSOPs)
2. Other quality assurance (QA) program
3. Certificate of Analysis
4. Certificate of Identity
5. Other *(Specify):* _____

2.4 Why does this plant **not** follow published GMPs?

Standard operating procedures (SOPs) detail a specific sequence of events to perform a task. SOPs may include sanitation or operation procedures.

2.5 Does this plant have standard operating procedures (SOPs)?

1. Yes
2. No Skip to the STOP box below

2.6 Is there written documentation of the SOPs?

1. Yes
2. No



Please Read Before Continuing!

In Sections 3 through 9, we ask about the procedures for personnel, buildings and facilities, equipment, quality control and laboratory operations, production and process controls, warehousing, and consumer complaints to protect against adulteration and contamination. For the purposes of this survey, **adulteration** includes the presence in a product of any poisonous or harmful substance that may make the product injurious to health, the presence of filth or any other contaminate in the product, less or more of an ingredient than the product label claims, and the manufacture of a product in insanitary conditions in which the product may have become contaminated or injurious to health.

For each specific procedure (e.g., procedures for personnel on disease control, personal cleanliness, and training), we ask about the following:

Are there written procedures? Written procedures can include posted signs, policy and procedure (P&P) manuals, and information posted on the company's internal website.

Does plant management verify and keep records that these procedures are being followed? **Verification** is the confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. Verification may include direct observation of monitoring procedures, internal audits, calibration of equipment at specified intervals, and records review. Records can include paper and electronic documentation.

Are records made of any corrective actions taken if the procedures are not followed? Corrective actions are the procedures to be followed when a deviation is discovered during the monitoring process. Records can include written and electronic documentation.

3 Personnel

Written procedures for **disease control** specify the conditions under which employees (including contract/temporary personnel) may not work in a dietary supplement plant. This includes but is not limited to illness; open lesions, including boils, sores, or infected wounds; or any other abnormal source of microbial contamination.

Written procedures for **personal cleanliness** specify the hygienic practices employees (including contract/ temporary personnel) shall follow to protect against adulteration and contamination. This includes but is not limited to wearing outer garments, gloves, and hairnets; washing hands thoroughly; and refraining from eating, drinking, chewing gum, and using tobacco.

Written procedures for **education, training, or experience** specify the training requirements for employees (including contract/temporary personnel) and how written records of training are maintained.

3.1 Are there written procedures for personnel on **disease control**?

1. Yes
2. No

3.2 Are there written procedures for personnel on maintaining **personal cleanliness**?

1. Yes
2. No

3.3 Are there written procedures ensuring that all personnel employed in the manufacturing process have the proper **education, training, or experience** needed to perform the assigned functions?

1. Yes
2. No

3.4 Does plant management verify and keep records that the procedures for personnel on disease control, personal cleanliness, and training are being followed?

1. Yes
2. No Skip to question 3.6

3.5 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

3.6 Are records maintained of personnel education, training, or experience?

1. Yes
2. No Skip to Section 4 on page 6

3.7 How long are records of personnel education, training, or experience maintained? (*Circle one and enter number of years if necessary.*)

1. Term of employment
2. _____ year(s) after expiration date
3. _____ year(s) from date of manufacture
4. Other (*Specify*): _____

4 Buildings and Facilities

Written procedures for **maintenance of the grounds** specify how the grounds about the plant shall be maintained to protect against adulteration. This includes but is not limited to properly storing equipment; maintaining roads, yards, and parking lots; and maintaining adequate drainage and operating systems for waste treatment and disposal.

- 4.1** What percentage of this plant's facilities are owned vs. leased? (Include warehouse facilities located at this plant. Total should sum to 100%.)
- | | | |
|-----------|---------|-------------|
| a. Owned | _____ % | square feet |
| b. Leased | _____ % | square feet |
| Total | 100% | square feet |

If 50% or more of this plant's facilities are **owned**, complete **questions 4.2 – 4.7**.

If 50% or more of this plant's facilities are **leased**, complete **questions 4.8 – 4.21**.

Owned Facilities

Written procedures for **general maintenance and sanitation of the building, fixtures, and other physical facilities** specify how the plant shall be maintained in a sanitary condition and kept in repair to prevent adulteration.

- 4.2** Are there written procedures on **maintenance of the grounds** about the plant?
1. Yes
 2. No

- 4.3** Are there written procedures on **general maintenance and sanitation of the building, fixtures, and other physical facilities** of the plant?
1. Yes
 2. No

Written procedures for **cleaning and sanitizing materials** specify that they be safe and adequate under the conditions of use and how they shall be used, held, and stored in a manner that protects against adulteration.

- 4.4** Are there written procedures on the storage and use of **cleaning and sanitizing materials**?
1. Yes
 2. No

Written procedures for **pest control** specify what measures shall be taken to exclude pests from processing areas and to protect against adulteration by pests.

- 4.5** Are there written procedures on **pest control**?
1. Yes
 2. No

- 4.6** Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?
1. Yes
 2. No Skip to Section 5 on page 9

- 4.7** Are records made of any corrective actions taken if procedures are **not** followed?
1. Yes, for some procedures
 2. Yes, for all procedures
 3. No
- Skip to Section 5 on page 9

Leased Facilities

Written procedures for **maintenance of the grounds** specify how the grounds about the plant shall be maintained to protect against adulteration. This includes but is not limited to properly storing equipment; maintaining roads, yards, and parking lots; and maintaining adequate drainage and operating systems for waste treatment and disposal.

- 4.8** What is the **remaining** term of the lease? (*Enter number of years or months.*)
- a. _____ years
 - b. _____ months

- 4.9** For leased facilities, who is primarily responsible for **maintaining the grounds** about the plant?
1. Plant management (lessee)
 2. Facility owner (lessor) Skip to question 4.11

- 4.10** For leased facilities, are there written procedures on **maintenance of the grounds** about the plant?
1. Yes Skip to question 4.12
 2. No Skip to question 4.12

- 4.11** Does plant management verify and keep records that the facility owner is properly **maintaining the grounds**?
1. Yes
 2. No

Written procedures for **general maintenance and sanitation of the building, fixtures, and other physical facilities** specify how the plant shall be maintained in a sanitary condition and kept in repair to prevent adulteration.

- 4.12** For leased facilities, who is primarily responsible for **general maintenance and sanitation of the buildings, fixtures, and other physical facilities** of the plant?
1. Plant management (lessee)
 2. Facility owner (lessor) Skip to question 4.15

- 4.13** For leased facilities, are there written procedures on **general maintenance and sanitation of the building, fixtures, and other physical facilities** of the plant?
1. Yes

2. No

Written procedures for **cleaning and sanitizing materials**

specify that they be safe and adequate under the conditions of use and how they shall be used, held, and stored in a manner that protects against adulteration.

4.14 For leased facilities, are there written procedures on the storage and use of **cleaning and sanitizing materials**?

1. Yes [Skip to question 4.17](#)
2. No [Skip to question 4.17](#)

4.15 Does plant management verify and keep records that the facility owner is properly **maintaining the buildings, fixtures, and other physical facilities** of the plant?

1. Yes
2. No

4.16 Does plant management verify and keep records that the **cleaning and sanitizing materials** used by the facility owner are being properly stored and used?

1. Yes
2. No

Written procedures for **pest control** specify what measures shall be taken to exclude pests from processing areas and to protect against adulteration by pests.

4.17 For leased facilities, who is primarily responsible for **pest control**?

1. Plant management (lessee)
2. Facility owner (lessor) [Skip to question 4.19](#)

4.18 For leased facilities, are there written procedures on **pest control**?

1. Yes [Skip to question 4.20](#)
2. No [Skip to question 4.20](#)

4.19 Does plant management verify and keep records that the facility owner is taking proper **pest control** measures?

1. Yes
2. No

4.20 Does plant management verify and keep records that procedures for buildings and facilities maintenance are being followed?

1. Yes
2. No [Skip to Section 5 on page 9](#)

4.21 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

5 Equipment

Written procedures for **cleaning, sanitizing, and maintaining equipment and utensils** specify how equipment and utensils shall be cleaned, sanitized, and maintained in a manner that protects against adulteration.

Validation is the examination and provision of objective evidence that equipment, instruments, and controls are accurate, adequately maintained, and adequate in number for the intended uses to measure, regulate, or record temperature, pH, water activity, or other condition.

5.1 Are there written procedures on the **cleaning, sanitizing, and maintaining of equipment and utensils**?

1. Yes
2. No **Skip to question 5.4**

5.2 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 5.4**

5.3 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

5.4 Does this plant **validate** that equipment, instruments, and controls are **installed** correctly?

1. Yes
2. No

5.5 Does this plant **validate** that equipment, instruments, and controls are **used** correctly?

1. Yes
2. No

5.6 Does this plant **validate** the equipment used in quality control? Quality control equipment includes automatic, mechanical, electronic, and computer equipment, including hardware and software.

1. Yes
2. No

6 Quality Control and Laboratory Operations

6.1 Is there a unit or person responsible for quality control?

1. Yes
2. No **Skip to question 6.4**

6.2 Are there written procedures on the responsibilities and procedures required of the quality control unit/person?

1. Yes
2. No

6.3 For which of the following does the quality control unit/person have responsibility and authority? (*Circle all that apply.*)

1. Approval/rejection of cleaning and maintenance procedures
2. Approval/rejection of procedures, specifications, controls, tests, and examinations for purity, quality, and composition
3. Approval/rejection of raw materials
4. Approval/rejection of packaging materials
5. Approval/rejection of labeling
6. Approval/rejection of finished dietary products
7. Other (*Specify*): _____

A **Certificate of Analysis** is a statement from the supplier about the identity, strength, quality, and purity of a dietary supplement raw material, ingredient, or finished product.

6.4 Does this plant require suppliers to provide a **Certificate of Analysis**? (*Circle only one.*)

1. Yes, from some suppliers
2. Yes, from all suppliers
3. No, do not require CofA from any suppliers **Skip to question 6.7**
4. Do not receive ingredients **Skip to question 6.7**

6.5 Does this plant verify the reliability of the suppliers' **Certificate of Analysis**?

1. Yes
2. No **Skip to question 6.7**

6.6 How is reliability of the suppliers' **Certificate of Analysis** verified? (*Circle all that apply.*)

1. Conduct on-site review of suppliers' operations
2. Perform tests in-house to confirm results
3. Use off-site laboratory to confirm results
4. Require suppliers to conduct tests as part of supply specifications
5. Standard reference materials
6. Other (*Specify*): _____

Raw materials are any ingredients intended for use in the manufacture of a dietary ingredient or dietary supplement, including those that may not appear in such finished product.

6.7 Does this plant conduct tests on any **raw materials**? (Circle all that apply.)

1. Yes, in-house
2. Yes, off-site
3. No Skip to question 6.14

6.8 What percentage of raw materials are sampled and tested? (Provide average for all raw materials.)

_____ % of lots

6.9 Which of the following testing techniques are used to confirm **identity of ingredients** for raw materials? (Circle all that apply.)

1. Physical
2. Chemical
3. Microbiological
4. Visual (macroscopic or microscopic)
5. Organoleptic
6. No tests are conducted to confirm identity of ingredients
7. Other (Specify): _____

6.10 Which of the following testing techniques are used for detecting **contamination** of raw materials? (Circle all that apply.)

1. Physical
2. Chemical
3. Microbiological
4. Visual (macroscopic or microscopic)
5. Organoleptic
6. No tests are conducted to detect contamination
7. Other (Specify): _____

6.11 Does this plant conduct chemical tests to determine **potency** of raw materials?

1. Yes
2. No

6.12 For the most recent fiscal year, approximately what percentage of raw materials was rejected because of the wrong identity, contamination, or potency? (If none, enter zero.)

_____ % of lots If zero, skip to question 6.14

6.13 What was the reason(s) for the rejection? (Circle all that apply. For each item circled, enter the percentage of raw materials rejected for this reason. The total should sum to 100%.)

- | | |
|--|-----------------|
| 1. Microbial contamination | _____ % of lots |
| 2. Pesticide, herbicide, fungicide contamination | _____ % of lots |
| 3. Other chemical contamination | _____ % of lots |
| 4. Wrong ingredient | _____ % of lots |
| 5. Subpotency | _____ % of lots |
| 6. Superpotency | _____ % of lots |
| 7. Aflatoxin or other toxin | _____ % of lots |

8. Other % of lots

In-process materials and/or finished products are any materials fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way that is produced for and used in the preparation of a dietary supplement.

6.14 Does this plant conduct tests on any ***in-process materials or finished products***?

1. Yes
2. No **Skip to question 6.21**

6.15 What percentage of in-process materials and/or finished products are sampled and tested? (*Provide an average for in-process materials and/or finished products; if none, enter zero. Include continuous monitoring.*)

- a. _____ % of in-process material batches
- b. _____ % of finished product batches

6.16 Which of the following testing techniques are used to confirm ***identity of ingredients*** for in-process materials and/or finished products? (*Circle all that apply.*)

1. Physical
2. Chemical
3. Microbiological
4. Visual (macroscopic or microscopic)
5. Organoleptic
6. No tests are conducted to confirm identity of ingredients
7. Other (*Specify*): _____

6.17 Which of the following testing techniques are used for detecting ***contamination*** of in-process materials and/or finished products? (*Circle all that apply.*)

1. Physical
2. Chemical
3. Microbiological
4. Visual (macroscopic or microscopic)
5. Organoleptic
6. No tests are conducted to detect contamination
7. Other (*Specify*): _____

6.18 Does this plant conduct chemical tests to determine ***potency*** of in-process materials and/or finished products?

1. Yes
2. No

6.19 For the most recent fiscal year, approximately what percentage of in-process materials and/or finished products was rejected because of the wrong identity, contamination, or potency? (*If none, enter zero.*)

- a. _____ % of in-process material batches
- b. _____ % of finished product batches

If zero, skip to question 6.21

6.20 What was the reason(s) for the rejection? (*Circle all that apply. For each item circled, enter the percentage of in-process materials and/or finished products rejected for this reason. The total should sum to 100%.*)

- | | |
|--|--------------------|
| 1. Microbial contamination | _____ % of batches |
| 2. Pesticide, herbicide, fungicide contamination | _____ % of batches |
| 3. Other chemical contamination | _____ % of batches |
| 4. Wrong ingredient | _____ % of batches |
| 5. Subpotency | _____ % of batches |
| 6. Superpotency | _____ % of batches |
| 7. Formulation with missing ingredient | _____ % of batches |
| 8. Aflatoxin or other toxin | _____ % of batches |
| 9. Other | _____ % of batches |

6.21 Which of the following testing methods are generally used for testing of raw materials, in-process materials, or finished products? (*Circle all that apply.*)

1. Association of Analytical Chemists (AOAC)
2. U.S. Pharmacopeia (USP)
3. British Herbal Pharmacopoeia
4. European Pharmacopoeia
5. Food Chemical CODEX (FCC)
6. American Chemical Society (ACS)
7. In-house methods
8. Other (*Specify*): _____
9. No testing conducted **Skip to question 6.24**

6.22 Does your testing policy specify the use of standard reference materials?

1. Yes
2. No **Skip to question 6.24**

6.23 What is the source of the standard reference materials? (*Circle all that apply.*)

1. Compendial reference standard
2. In-house **primary** reference materials
3. In-house **working** reference materials
4. Other (*Specify*): _____

6.24 Does your plant hold representative reserve samples of each batch manufactured?

1. Yes
2. No **Skip to question 6.26**

6.25 How long do you hold representative reserve samples?

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

Written procedures for **laboratory operations** specify the procedures that shall be used to assure that dietary supplement products conform to appropriate standards of purity, quality, and composition and that packaging materials are safe and suitable for their intended purpose.

6.26 Are there written procedures for **laboratory operations**?

1. Yes
2. No **Skip to question 6.31**
3. Do not have laboratory operations
Skip to Section 7 on page 15

6.27 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 6.29**

6.28 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

6.29 Do your written procedures for laboratory operations include any of the following? (*Circle all that apply.*)

1. Sample selection, method description, validation of methodology and results, acceptance/rejection criteria, and use of test results
2. Methods for determining ingredient identity and for detecting adulteration
3. Tests to assess the stability characteristics of products in determining appropriate storage conditions and expiration dating (include testing conducted at corporate headquarters)
4. Procedures for handling and filing test records

6.30 How long are records for laboratory operations retained? (*Circle one and enter number of years.*)

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

6.31 Does this plant verify and keep records that laboratory equipment is calibrated correctly?

1. Yes
2. No

7 Production and Process Controls

Written procedures for **receipt of dietary supplement ingredients** specify the criteria for accepting dietary supplement ingredients.

7.1 Are there written procedures for **receipt of dietary supplement ingredients**?

1. Yes
2. No **Skip to question 7.6**
3. Do not receive dietary supplement ingredients
Skip to question 7.6

7.2 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 7.4**

7.3 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

7.4 Do your written procedures for receipt of dietary supplement ingredients include any of the following? (*Circle all that apply.*)

1. Written acceptance criteria for dietary supplement ingredients developed by a competent individual
2. Certificate of Analysis specifications
3. Representative sample and authenticated plant reference held in an environmentally appropriate repository for each receiving and production lot/batch
4. Records linking the Certificate of Analysis to the identity of the unprocessed raw material and to the finished product
5. Records to trace and verify compliance with laws on harvest of wildcrafted botanicals
6. Audit records concerning the reliability of supplier Certificate of Analysis
7. Records for source of animal derived materials or products
8. Records for fish and fishery demonstrating that FDA fish and fishery products HACCP regulations are followed
9. Records for raw materials to assure segregation of raw, in-process, and finished product and protection against adulteration

7.5 How long are records on receipt of dietary supplement ingredients retained? (*Circle one and enter number of years.*)

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

Written procedures for **production processes** specify the requirements of master and batch production and control records.

7.6 Are there written procedures for **production processes**?

1. Yes
2. No **Skip to question 7.11**
3. No production processes conducted
Skip to Section 8 on page 18

7.7 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 7.9**

7.8 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

7.9 Do your written procedures for production processes include any of the following? (*Circle all that apply.*)

1. Master production and control records
2. Batch production and control records
3. Equipment use and cleaning records, including dates of use and product and lot number of each batch processed
4. Records that demonstrate that automatic equipment, including mechanical and electronic equipment (computers), used in the manufacturing process is designed, installed, tested, calibrated, validated, maintained, and checked to ensure that they are capable of and are performing the intended functions
5. Records for reprocessing of a product
6. Records to assure that correct labels and labeling and safe packaging materials are used
7. Records to permit tracking the history of the manufacturing process
8. Reserve samples of each batch of dietary supplement product are retained and stored under conditions consistent with the product labeling

7.10 How long are records on production processes retained? (*Circle one and enter number of years.*)

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

7.11 Does this plant use production and process controls that identify the points, steps, or stages in the manufacturing process to prevent adulteration?

1. Yes
2. No **Skip to Section 8 on page 18**

7.12 Does this plant's production and process controls have specifications that must be met for identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements and packing and labeling materials? (*Circle all that apply.*)

1. Yes, for components

2. Yes, for ingredients
3. Yes, for dietary supplements
4. Yes, for packing and labeling materials
5. No, none of the above

7.13

Does this plant conduct tests to monitor the production and in-process control points, steps, or stages to ensure the identity, purity, quality, strength, and composition of components, ingredients, or dietary supplements? *(Circle all that apply.)*

1. Yes, for components
2. Yes, for ingredients
3. Yes, for dietary supplements
4. No, none of the above

8 Warehousing

Written procedures for **storage procedures** specify how finished products shall be stored to protect against adulteration and deterioration.

8.1 Does your warehouse have temperature or humidity controls? (*Circle all that apply.*)

1. Temperature controls
2. Humidity controls
3. No temperature or humidity controls

8.2 Are there written procedures for **storage procedures** to control against physical, chemical, and microbial adulteration as well as deterioration of the product and container?

1. Yes
2. No **Skip to question 8.7**

8.3 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 8.5**

8.4 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

8.5 Do your written procedures for warehousing include any of the following? (*Circle all that apply.*)

1. Procedures and records for forward and backward tracing of product
2. Procedures and records for salvaged products that include product examination and reprocessing as appropriate

8.6 How long are records on warehousing retained? (*Circle one and enter number of years.*)

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

8.7 Are there written procedures on proper precautions to **reduce the potential for mix-ups or adulteration or contamination** of ingredients, raw materials, or in-process formulations (e.g., safety controls and operating practices or separation of ingredients)?

1. Yes
2. No **Skip to Section 9 on page 20**

8.8 Does plant management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to Section 9 on page 20**

8.9 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

9 Consumer Complaints

Written procedures for **consumer complaints** specify how all written and oral complaints regarding products are handled.

9.1 Are there written procedures at the plant or corporate level for handling **consumer complaints**?

1. Yes
2. No **Skip to question 9.6**

9.2 Does management verify and keep records that these procedures are being followed?

1. Yes
2. No **Skip to question 9.4**

9.3 Are records made of any corrective actions taken if procedures are **not** followed?

1. Yes, for some procedures
2. Yes, for all procedures
3. No

9.4 Do your written procedures for handling consumer complaints include any of the following? (*Circle all that apply.*)

1. Procedures for handling all written and oral complaints
2. Records concerning the handling of complaints including any investigations, investigation findings, and follow-up action taken
3. Procedures for requiring reporting of serious adverse events to FDA MEDWATCH

9.5 How long are records on consumer complaints retained at the plant or corporate headquarters? (*Circle one and enter number of years.*)

1. _____ year(s) after expiration date
2. _____ year(s) from date of manufacture
3. Other (*Specify*): _____

9.6 What are your procedures for handling adverse events associated with consumer complaints? (*Circle all that apply.*)

1. Incident is reported to FDA
2. Product is tested for identity and composition
3. Product is reformulated
4. Product is recalled
5. Other (*Specify*): _____

9.7 Does this plant have a recall procedure in place?

1. Yes
2. No

9.8

Who evaluates reports on consumer complaints? (*Circle all that apply.*)

1. In-house medical personnel
2. In-house scientific personnel
3. In-house quality control personnel
4. In-house regulatory affairs personnel
5. Outside contractor
6. Other (*Specify*): _____

10 Your Plant

10.1 What was the calendar year during which this plant was built? *(If multiple buildings, use date of oldest building.)*

10.2 What was the calendar year during which the **dietary supplement operations** began at this plant? *(If multiple buildings, use date of earliest operation.)*

10.3 What is the total square footage of this plant? *(Include warehouse facilities.)*

_____ square feet

10.4 Are this plant's facilities connected to a city water supply?

1. Yes **Skip to question 10.6**
2. No

10.5 Is the water supply at this plant potable?

1. Yes
2. No

10.6 Does your company own plants at other locations?

1. Yes
2. No

10.7 How many employees are currently employed at this plant? *(Include contract/temporary employees.)*

- a. Full-time _____
- b. Part-time _____

10.8 How many employees employed at this plant are working in **quality control**? *(Include contract/temporary employees.)*

- a. Full-time _____
- b. Part-time _____

10.9 For the most recent fiscal year, provide the number of batches of **dietary supplement** product by product form. *(Enter the number of batches for each form; if none, enter zero.)*

- a. Powder _____ batches
- b. Liquid _____ batches
- c. Paste _____ batches
- d. Capsule _____ batches
- e. Tablet or caplet _____ batches
- f. Gelcap _____ batches

- g. Other (Specify): _____ batches
- h. Other (Specify): _____ batches
- Total _____ batches

10.10 What were the gross sales revenue for the **dietary supplement operations only** at this plant for the most recent fiscal year? (Your responses will be kept completely confidential; that is, information identifying your plant will not be linked to your responses. Do not include nonsales revenue such as interest income.)

- 1. Less than \$500,000
- 2. \$500,000 – \$1 million
- 3. \$1 – \$2.5 million
- 4. \$2.5 – \$5 million
- 5. \$5 – \$10 million
- 6. \$10 – \$20 million
- 7. \$20 – \$50 million
- 8. \$50 – \$100 million
- 9. \$100 – \$500 million
- 10. Over \$500 million