

NNFA GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS

Background:

On October 25, 1994, the Dietary Supplement Health and Education Act (DSHEA) was signed into law. One provision of DSHEA was that “The Secretary may by regulation prescribe good manufacturing practices (GMP) for dietary supplements. Such regulations shall be modeled after GMP regulations for food and may not impose standards for which there is no current and generally available analytical methodology. No standard of GMP may be imposed unless such standard is included in regulation promulgated after notice and opportunity for comment....”

Proposed Supplement GMP:

As a proactive step, representatives of the dietary supplement industry met with the FDA, on November 30, 1995, and submitted a document that outlined proposed GMP for dietary supplements. The objectives of the GMP, as stated by the industry representatives, were to ensure that consumers were provided with dietary supplement products that: 1) are safe and not adulterated or misbranded; 2) have the identity and provide the quantity of dietary ingredients declared in labeling; and that 3) meet the quality specifications that the supplement is represented to meet.

The industry submission was patterned after the GMP for food regulations as outlined in 21CFR. 110, but also contained some additional requirements that the industry representatives considered “essential to the manufacture of safe and properly labeled dietary supplements”. Significant differences between supplement GMP and food GMP include: 1) the requirement for identity testing of raw materials; 2) the requirement for a quality control unit; 3) the provision for expiration dating; 4) the requirement for master and batch production and control records; 5) expanded requirements for the use of production and process controls; 6) expanded requirements for written procedures and records; and 7) expanded requirements for the storage and distribution of final products, including procedures for handling complaints and returned products.

The FDA published the industry suggested dietary supplement GMP in the Federal Register (62, #25, 5700-5709, 2/6/97) and solicited comments from industry, consumers, and other interested parties, on the need for dietary supplement GMP regulations and on the requirements that should be included in such regulations. The Preamble stated that “These GMP are modeled after GMP for foods. Provisions have been adopted, modified or expanded as appropriate, considering the special requirements applicable to the manufacture of dietary supplements and dietary ingredients. There is no desire or intent to impose on dietary supplements the type of documentation and validation currently required in the manufacture of pharmaceutical products.”

NNFA Supplement GMP:

There is a wide diversity of product types, manufacturing and distribution operations, and the size and resources available, within the dietary supplement industry. NNFA also recognizes that there are a variety of ways to meet individual requirements of GMP and that different approaches and procedures may be most suitable and appropriate for individual companies. In order to address the diverse needs of the Industry and the need to develop a comprehensive set of GMP that are applicable, useful and suitable for all member companies, NNFA has redrafted the proposed supplement GMP, developed by the Industry and published in the Federal Register. This redraft retains all the requirements (“the what”) specified in the industry draft, but some of the detailed procedures (“the how”) have been eliminated, to produce a more

concise set of GMP that is applicable to all types of companies within the industry. As such, the NNFA GMP contains all of the requirements of the proposed GMP while allowing the user considerable flexibility in how they meet the specified requirements.

The Company that holds the product label has ultimate responsibility for the assurance that a dietary product is manufactured according to GMP at all stages in the supply chain, from acquisition of raw materials through final product testing and distribution. Adherence to GMP is also a requirement of all subcontractors and distributors used by the holder of the product label. Two additional requirements have been added to the NNFA GMP. These additions are: 1) the requirement that a shelf life statement shall be mandatory for all finished products, and 2) the requirement that all test methods shall be reliable and yield reproducible results to ensure the continuing reliability of the data.

Version 01/01/1999 – Approved by the NNFA Board of Directors, December 1998
Effective Date, January 1, 1999

Version 01/01/2000 – Approved by the NNFA Board of Directors, November 1999
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I Personnel

(a) Disease Control:

- (1) Any person who has, by medical examination or supervisory observation, an illness or medical condition such as open lesions or infected wounds that could be a possible source of microbial contamination, **SHALL** be removed from the manufacturing process so as to prevent adulteration of the dietary product during manufacture and storage. Personnel **SHALL** be instructed to report such health conditions to their supervisors.
- (2) Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

(b) Cleanliness:

- (1) All personnel having direct contact with raw materials, in-process materials, exposed products, and packaging components, as well as those individuals utilizing processing equipment and utensils, **SHALL** conform to a level of basic hygiene and personal cleanliness to protect the product against adulteration. These methods may include, but are not limited to:
 - (i) Wearing outer garments that protect against adulteration of product and equipment.
 - (ii) Maintaining personal cleanliness.
 - (iii) Washing hands thoroughly before starting work and at any other time when the hands may have become soiled or contaminated.
 - (iv) Removing all unsecured jewelry and hand jewelry, or covering hand jewelry that cannot be removed.
 - (v) Using gloves that are maintained in an intact, clean and sanitary condition.
 - (vi) Wearing hair nets, caps, beard covers, arm covers, or other effective hair restraints.
 - (vii) Storing clothing or other personal effects outside of processing areas.
 - (viii) Excluding the consumption of food and drink, as well as the use of chewing gum and tobacco products.
- (2) Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

(c) Education and Training:

- (1) All personnel **SHALL** have written job descriptions and possess education, training and/or experience to perform their assigned function. All personnel **SHALL** receive GMP education and training to perform their assigned function.
- (2) Written records of education and training **SHALL** be retained and routinely updated in order to document education and training progress.

(d) Supervision:

- (1) The responsibility for assuring compliance by all personnel to these requirements **SHALL** be assigned to qualified personnel with the proper education, training and/or experience.

II Plant and Grounds

(a) Grounds:

- (1) The grounds about a manufacturing plant **SHALL** be kept in a condition that will protect against the adulteration of the product. Methods include, but are not limited to:
 - (i) Properly storing equipment and removing litter, refuse and vegetation within the immediate vicinity of buildings that could attract or harbor pests.
 - (ii) Maintaining roads, yards and parking lots, and draining areas that could contribute to product adulteration or harbor pests
 - (iii) Disposal of all waste and rubbish so as to prevent adulteration of the dietary product during manufacture and storage, and to ensure a clean, safe work environment.
- (2) Written procedures **SHALL** be established and followed that define the standard requirements for these practices.

(b) Plant Construction and Design:

- (1) Plant buildings and structures **SHALL** be of a size, construction and design to facilitate maintenance, cleaning and sanitary operation, and to prevent mix-ups between different raw materials and products. The plant and facilities **SHALL**:
 - (i) Provide sufficient space for the placement of equipment and the storage and segregation of materials.
 - (ii) Provide operating practices or effective design that reduces the potential for mix-ups or adulteration of in-process or finished products.
 - (iii) Facilitate maintenance functions including cleaning, sanitation, waste treatment and disposal, and the elimination and prevention of pest infestations.
 - (iv) Provide adequate lighting in manufacturing areas.
 - (v) Provide safety-type light bulbs, fixtures, and skylights to protect product against possible adulteration by glass.
 - (vi) Provide ventilation, air filtration, heating and/or cooling to control microorganisms, dust, humidity, and temperature in order to prevent adulteration of dietary product, and provide a safe, clean work environment.
 - (vii) Provide screening or other protection against pests.

III Sanitation of Buildings and Facilities

(a) General Maintenance:

- (1) All buildings, structures, fixtures and equipment **SHALL** be constructed in such a manner that floors, walls, ceilings, work surfaces and equipment can be cleaned and sanitized. All buildings and fixtures **SHALL** be maintained in a sanitary condition and **SHALL** be kept in good repair.
- (2) Written records **SHALL** be maintained that document cleaning of process rooms and areas.

(b) Cleaning and Sanitizing Agents:

- (1) Cleaning and sanitizing agents, pesticide chemicals, and fungicides **SHALL** be safe and effective for their intended use.
- (2) Cleaning and sanitizing agents, pesticide chemicals, and fungicides **SHALL** be identified, used, held and stored in a manner that protects against adulteration of raw materials, in-process or finished products, or contamination of processing equipment, utensils or packaging materials.

- (c) Pest Control:
- (1) Effective measures **SHALL** be taken to exclude pests from the processing areas and the entire Plant. The use of insecticides or rodenticides is permitted only under precautions and restrictions that protect against adulteration of raw materials, products, equipment or packaging materials.
 - (2) Written records of pest control inspections **SHALL** be maintained.
- (d) Water Supply:
- (1) Potable water, as a minimum quality water, at designated temperature and pressure, **SHALL** be provided in all areas where required for processing, cleaning, or for employee sanitary facilities. Water **SHALL** meet the standards prescribed in the EPA's Primary Drinking Water Regulations (40 CFR part 141).
 - (2) Procedures **SHALL** be established and followed to assure that water used in processing operations meets microbial standards prescribed in the EPA's Primary Drinking Water Regulations (40 CFR part 141).
- (e) Plumbing:
- (1) Plumbing **SHALL** be of a size and design and installed and maintained to:
 - (i) Carry sufficient quantities of water to required locations throughout the plant.
 - (ii) Properly convey sewage and liquid waste from the plant.
 - (iii) Avoid adulteration of product or contamination of water supplies or equipment.
 - (iv) Provide floor drainage in areas where floors are subject to flooding.
 - (v) Prevent the contamination of fresh water with discharge wastewater or sewage.
- (f) Sewage Disposal:
- (1) Sewage disposal **SHALL** be made into a sewage system.
- (g) Toilet Facilities:
- (1) Each Plant **SHALL** provide its employees with readily accessible toilet facilities.
 - (2) Each Plant **SHALL** maintain the toilet facilities in a sanitary condition and in good repair at all times.
 - (3) Each Plant should provide self-closing doors that do not open into areas where materials and/or product are exposed to airborne contamination.
- (h) Hand-washing Facilities:
- (1) Hand-washing facilities shall be convenient and furnished with running water and **SHALL** include:
 - (i) Hand-washing facilities at each location where employees are required to wash their hands.
 - (ii) Effective hand-cleaning and sanitizing preparations.
 - (iii) Air dryers or sanitary towel services.
 - (iv) Devices or fixtures that protect against the recontamination of clean, sanitized hands.
 - (v) Signs directing employees to wash hands before they start work, after each absence from their work station, or when their hands have become soiled or contaminated.
- (i) Rubbish Disposal:
- (1) Refuse receptacles and rubbish disposal practices that protect against adulteration or the harborage of pests **SHALL** be provided.

(j) Supervision:

- (1) The overall sanitation of the Plant **SHALL** be under the supervision of a qualified individual(s), with qualifications based on education, experience and/or training.

IV Equipment and Utensils

(a) Design and Construction:

- (1) Equipment **SHALL** be installed and maintained so as to facilitate the cleaning of the equipment and of the surrounding areas.
- (2) Equipment and utensils having direct contact with dietary product **SHALL** be constructed of inert, non-toxic materials and designed to withstand the environment to which it is subjected during the manufacturing process and during cleaning.
- (3) Seams on utensils and processing equipment **SHALL** be smoothly bonded or maintained to minimize the accumulation of residues and the opportunity for growth of microorganisms.
- (4) All Plant equipment and utensils **SHALL** be so designed, constructed, and maintained as to preclude the adulteration of raw materials, packaging materials, in-process materials, and finished product with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.
- (5) Cleaners, sanitizers, lubricants, and/or coolants used on utensils and processing equipment **SHALL** be suitable for use in food processing.
- (6) All equipment with critical parameters that require monitoring **SHALL** have suitable measuring devices such as time, temperature, pressure and/or speed controls, etc.
- (7) Each freezer and cold storage compartment **SHALL** be fitted with a temperature-measuring device, automatic control, or alarm system.
- (8) Compressed air and other gases that come into contact with a dietary product or dietary ingredient or used to clean equipment or utensils **SHALL** be treated in such a way that the materials they come in contact with are not adulterated.
- (9) Written procedures **SHALL** be established and followed that define the performance of routine preventative maintenance. Records **SHALL** be retained that document equipment maintenance.
- (10) Instruments and controls **SHALL** be accurate and maintained. Written records **SHALL** be retained that document maintenance and calibration of equipment.

(b) Sanitation of Equipment and Utensils:

- (1) All utensils and equipment **SHALL** be cleaned, as frequently as necessary, using safe cleaning and sanitizing agents, and then stored in a manner that protects against recontamination.
- (2) Written procedures **SHALL** be established and followed for cleaning and maintaining equipment and utensils.
- (3) A written record of major equipment cleaning and use **SHALL** be maintained in individual equipment logs that show the date, product and lot number of each batch processed, and the cleaning and/or maintenance performed. The person(s) performing the cleaning and/or maintenance **SHALL** record in the log that the work was performed. Entries in the log should be in chronological order.

V Quality Control and Laboratory Operations

(a) Quality Control Operations

- (1) Quality control operations **SHALL** be employed to assure that dietary products conform to standards of purity, quality and composition, and that packaging materials are safe for their intended purpose.

(b) Quality Control Unit:

- (1) There **SHALL** be a quality control unit that has the responsibility and authority to:
 - (i) Approve or reject all procedures, specifications, test methods and results that impact the purity, quality, and composition of an ingredient or product.
 - (ii) Approve or reject all raw materials, packaging materials, labeling and finished products, including contract-manufactured products, based upon conformance to established specifications.
 - (iii) Assure that completed production records are reviewed and **SHALL** have the final authority to determine if the product is approved for distribution. This evaluation **SHALL** be documented and maintained as part of the batch record.
 - (iv) Establish procedures for changing or revising all documentation (such as procedures, methods, record keeping, formulas, etc.).
 - (v) Review and approve all changes to documentation (such as procedures, methods, record keeping, formulas, etc.).
 - (vi) Assure that the most current revision of all documentation (such as procedures, methods, record keeping, formulas, etc.) is in use at all times.
- (2) These responsibilities and authorities **SHALL** be established in writing and followed.

(c) In-house and/or Contract Laboratories:

- (1) In-house and/or contract laboratories **SHALL** be available for performance of the above tasks and responsibilities, and these responsibilities **SHALL** be established in writing and followed.

(d) Test Methods:

- (1) All test methods **SHALL** be reliable and yield reproducible results.

(e) Laboratory Records:

- (1) Laboratory records **SHALL** be maintained of data derived from all specified tests.

(f) Shelf Life:

- (1) All products **SHALL** bear an expiration date or a statement of product shelf life. These dates **SHALL** be supported by data to assure that the product meets established specifications throughout the product shelf life.
- (2) Accelerated stability studies or data from similar product formulations may be used for an initial determination of shelf life. Product shelf life **SHALL** be confirmed and may be extended on the basis of real time studies on product stored under labeled storage conditions.

VI Production and Process Controls

(a) Master Production and Control Records:

- (1) A master production and control record **SHALL** be prepared for the manufacture of each product, and **SHALL** be reviewed and approved by the quality control unit.
- (2) Master production and control records **SHALL** include:
 - (i) A complete list of raw materials used in the manufacture of the product, designated by names or codes sufficiently specific to indicate any special quality characteristic(s).
 - (ii) The amount of each raw material used. Each batch shall be formulated to provide not less than 100% of each claimed dietary ingredient.
 - (iii) The name and weight or measure of each dietary ingredient per unit or portion, or per unit of weight or measure of the product.

- (iv) A statement concerning any calculated excess of dietary ingredient contained in the product.
 - (v) A statement of the total weight or measure of any dietary supplement unit.
 - (vi) A statement of the theoretical weight or measure of the manufactured product and the acceptable range beyond which an investigation is required.
 - (vii) A description of the product container(s), closure(s), and finished product packaging labels, including positive identification of all labeling used.
 - (viii) Manufacturing and process control instructions.
- (b) Batch Production and Control Records:
- (1) Batch production and control records **SHALL** be prepared and followed for each batch of product. These records **SHALL** be an accurate representation of the master production and control record and **SHALL** include documentation that each significant step in the manufacturing process was accomplished, including:
 - (i) Dates;
 - (ii) Identity of individual major equipment and lines used;
 - (iii) Specific identification, including lot number, of each raw material or in-process material used;
 - (iv) Weight or measure of each raw material used in the course of processing;
 - (v) In-process testing results, if performed;
 - (vi) Quality control results;
 - (vii) Inspection of the packaging and labeling areas;
 - (viii) A statement of the actual yield at the conclusion of the manufacture and a statement of the percentage of theoretical yield, as appropriate;
 - (ix) Label control records, including specimens, copies or records of all labels used;
 - (x) Description of product containers and closures used;
 - (xi) Description of any sampling performed;
 - (xii) Any special notes of investigations or deviations from the described process.
 - (xiii) Identification of the persons performing and directly supervising described process.
 - (2) Any deviations from written and approved specifications, standards and test methods **SHALL** be recorded on the batch record, and justified.
- (c) Handling and Storage of Raw Materials, In-process Materials and Rework:
- (1) Raw materials, in-process materials and rework **SHALL** be stored under conditions that will protect against adulteration and minimize deterioration.
 - (2) Containers of raw materials **SHALL** be inspected upon receipt to assure that their condition has not contributed to the adulteration or deterioration of the contents.
 - (3) Raw agricultural materials that contain soil, or other contaminants, **SHALL** be washed or cleaned, as necessary.
 - (4) Raw materials, in-process materials, and rework **SHALL** be held in bulk, or in containers and under conditions of temperature and humidity that prevents the material from becoming adulterated or contaminated.
 - (5) Written procedures **SHALL** be established and followed for the receipt, identification, examination, handling, sampling, testing, and approval or rejection of raw materials.
 - (6) Each lot of raw material **SHALL** be identified with a distinctive lot number and **SHALL** be controlled according to its status (e.g. quarantined, approved, or rejected).
 - (7) Each lot of raw material, in-process material, and rework **SHALL** be examined or tested for filth, insect infestation, or other visually evident extraneous materials, microbial contamination, aflatoxin or other natural toxins, and all other established specifications, as necessary.

- (8) Each manufacturer **SHALL** have in place procedures to verify the identity of each lot of raw material.
 - (9) Approved raw materials **SHALL** be rotated so the oldest approved stock is used first.
 - (10) Raw materials **SHALL** be retested or reexamined after a specified time in storage or after exposure to conditions that are likely to adversely affect the purity, quality, or composition of the raw material.
 - (11) Rejected raw materials **SHALL** be identified and controlled under a system that prevents their use in manufacturing or processing operations.
- (d) Manufacturing Operations:
- (1) All inspection, manufacturing, packaging and storage operations **SHALL** be conducted in accordance with sanitation principles, in a manner that protects against adulteration and under conditions that minimize the potential for the growth of microorganisms.
 - (2) Written procedures **SHALL** be established and followed for all inspection, manufacturing, packaging and storage operations.
 - (3) Effective measures **SHALL** be taken to segregate raw materials, packaging materials, in-process materials, rework, and finished products.
 - (4) All containers, processing lines and major equipment used during the production of a batch **SHALL** be identified at all times to indicate their contents.
 - (5) Effective measures **SHALL** be taken to protect against the inclusion of metal or other extraneous material in the product, including the use of sieves, traps, magnets and metal detectors.
 - (6) Effective measures **SHALL** be taken for the identification, storage, and disposal of rejected or adulterated products.
 - (7) Written procedures **SHALL** be established and followed that describe tests to be conducted to assure the purity, composition and quality of the finished product
 - (8) Written procedures **SHALL** be established and followed for reprocessing batches that do not conform to finished goods standards or specifications.
- (e) Packaging and Labeling Operations:
- (1) Filling, assembling, packaging and other operations **SHALL** be performed in such a way that products are protected against adulteration.
 - (2) Written procedures **SHALL** be established and followed for the receipt, storage and examination of packaging materials.
 - (3) Labels for each different product type, strength, or quantity of contents **SHALL** be stored separately.
 - (4) Obsolete labels, labeling, and other packaging materials **SHALL** be destroyed and such destruction documented.
 - (5) Written procedures **SHALL** be established and followed to assure that the correct labels and packaging materials are issued and used.
 - (6) Packages **SHALL** be identified with a lot number that permits determination of the history of the manufacture and control of the batch.
 - (7) Packaging **SHALL** be examined to provide assurance that containers and packages in the lot have the correct label and lot number.

VII Warehousing, Distribution and Post-Distribution Procedures

- (a) Storage and Distribution:
- (1) Storage and transportation of finished product **SHALL** be conducted under conditions that protect the product against physical, chemical, and microbial adulteration, as well as deterioration of the product and the container.

- (2) Distribution records **SHALL** be maintained and retained by the manufacturer for at least 1 year beyond the expiration or shelf life date, whereby an effective product recall can be achieved.
- (b) Reserve Samples:
- (1) A reserve sample of each batch of a product **SHALL** be retained and stored under conditions consistent with the product labeling until at least 1 year after the expiration or shelf life date.
 - (2) The reserve sample should be stored in the same container/closure system in which the finished product is marketed and **SHALL** be at least twice the quantity necessary to perform all the required tests.
- (c) Records Retention:
- (1) Any laboratory, production, control or distribution record **SHALL** be retained for at least 1 year after the expiration or shelf life date of the batch.
 - (2) Raw material records **SHALL** be maintained for at least 1 year after the expiration or shelf life date of the last batch of product incorporating the raw material.
- (d) Written Recall Procedures:
- (1) Written procedures **SHALL** be established and followed that define the recall of a dietary product should said event become necessary.
- (e) Complaint Files:
- (1) Written procedures **SHALL** be established and followed for the handling of all written and oral product complaints. Such procedures **SHALL** provide for review by the quality control unit and the determination of the need for an investigation.
 - (2) A written record of each complaint **SHALL** be maintained until at least one year after the expiration or shelf life date of the product, or one year after the date that the complaint was received, whichever is longer. The written record **SHALL** include, where known, name and description of the product, lot number, source and nature of the complaint, and response, if any. Where an investigation is conducted, the written record **SHALL** include the findings of the investigation and follow-up action taken.
- (f) Returned Products:
- (1) Returned products **SHALL** be identified as such and held. The returned product **SHALL** be destroyed unless examination, testing, or other investigations prove the product meets standards of purity, composition, and quality.
 - (2) A returned product may be reprocessed provided that the subsequent product meets specifications.
 - (3) Records pertaining to returned, reprocessed and redistributed products **SHALL** be maintained and **SHALL** include the name and description of the product, lot number, reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned product.
- (g) Product Salvaging:
- (1) Products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures **SHALL** not be salvaged and returned to the marketplace.

(h) Defect Action Levels:

- (1) Some dietary ingredients and dietary supplements, even when produced under GMP, contain natural or unavoidable defects that at low levels are not hazardous to health. The FDA has established maximum levels for these defects in foods produced under GMP and uses these levels in deciding whether to recommend regulatory action.
- (2) Defect action levels may also be established for dietary products whenever it is necessary and feasible to do so. The manufacturer of a dietary product **SHALL** at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.
- (3) The mixing of a dietary ingredient or dietary supplement containing defects above any established defect action level with another lot of dietary ingredient or dietary supplement is not permitted and renders the final lot adulterated within the meaning of the act, regardless of the defect level of the final product.

Glossary

“**Act**” means the Federal Food, Drug and Cosmetic act as amended (21 USC 301 et seq.)

“**Adequate**” means that which is needed to accomplish the intended purpose in keeping with good public health practice.

“**Adulteration**” as defined by the Federal Food and Cosmetic Act, §402, ADULTERATED FOOD that can be found 21 USC 342

“**Batch**” or “**Lot**” means a specific quantity of a finished product or other material that is intended to have uniform character and quality, within specified limits, and/or is produced according to a single manufacturing order during the same cycle of manufacture.

“**Botanical Ingredient**” means the plant species or form.

“**Composition**” means:

1. the identity of a dietary ingredient or dietary supplement, and
2. the concentration of a dietary ingredient (e.g. weight or other unit of use/weight or volume), or the potency or activity of one or more dietary ingredients, as indicated by appropriate procedures.

“**Contract-Manufactured**” means products manufactured, in whole or in part, for the supplier, by a subcontractor.

“**Dietary ingredient**” means an ingredient intended for use or used in a dietary supplement that is:

1. a vitamin
2. a mineral
3. a herb or other botanical
4. an amino acid
5. a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or
6. a concentrate, metabolite, constituent, extract, or combination of any of the foregoing ingredients

“**Dietary product**” means either a dietary ingredient or dietary supplement as defined in this part.

“**Dietary supplement**” means dietary supplement as defined in section 201(ff) of the act.

“**Procedures SHALL be established and followed**” means procedures are currently in place and followed by all appropriate personnel.

“**Expiration date**” is the date beyond which the product may no longer conform to specifications.

“**Identify**” means testing for origin, nature, form and characteristic, or taxonomic classification.

“In-process material” means any material 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 product.

“Lot” means “batch” as defined above.

“Lot number” means any distinctive combination of letters, numbers, or symbols, or any combination of them from which the complete history of the manufacture, processing, packing, holding and distribution of a batch or lot of a finished dietary ingredient, dietary supplement or other material can be determined.

“Manufacture” or “Manufacturing” includes all operations associated with the production of dietary products, including packaging, and labeling operations, testing, and quality control of a dietary ingredient or dietary supplement.

“Microorganisms” means yeast, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that a dietary ingredient or dietary supplement is contaminated with filth or otherwise may cause a dietary product to be adulterated.

“Pest” refers to any objectionable animals or insects including, but not limited to bird, rodents, flies, and larvae.

“Plant” means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of a dietary product.

“Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent a dietary product from being adulterated.

“Quality control unit” means any person or organizational element designated by the firm to be responsible for the duties relating to quality control operations.

“Raw material” means any ingredient intended for use in the manufacture of a dietary ingredient or dietary supplement, including those that may not appear in such finished product.

“Representative sample” means a sample that consists of a number of units that are drawn based upon a rational criteria, such as random sampling, and is intended to assure that the sample accurately portrays the material being sampled.

“Rework” means clean, unadulterated material that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use in the manufacture of a dietary product.

“Sanitize” means to treat equipment, containers, or utensils by a process that is effective in destroying vegetative cells or microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

“SHALL” is used to state mandatory requirements.

“Shelf life” is the length of time during which the product exhibits stability.

“**Should**” is used to state recommended or advisory procedures or identify recommended equipment.

“**Specifications**” are the quality parameters to which the products or materials must conform and which serve as a basis for quality evaluation.

“**Stability**” is the continued conformance of the product to its specifications.

“**Standard Operating Procedure**” is a written authorized procedure, which gives instructions for performing operations.