Subpart A--General Provisions

Sec.

Subpart A--General Provisions

§ 111.1 Who is subject to these regulations?

You are subject to the regulations in this part if you manufacture, package, or hold a dietary ingredient or dietary supplement.

§ 111.2 What are these regulations intended to accomplish?

The regulations in this part establish the minimum current good manufacturing practices that you must use to the extent that you manufacture, package, or hold a dietary ingredient or dietary supplement.

§ 111.3 What definitions apply to this part?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) apply to such terms when used in these regulations. For the purpose of these regulations, the following definitions also apply:

Actual yield means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular

dietary ingredient or dietary supplement.

Batch means a specific quantity of a dietary ingredient or dietary supplement that is intended to meet specifications for identity, purity, quality, strength, and composition, and is produced during a specified time period according to a single manufacturing record during the same cycle of manufacture.

Batch number, lot number, or control number means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, or holding of a batch or lot of dietary ingredients or dietary supplements can be determined.

Component means any substance intended for use in the manufacture of a dietary ingredient or dietary supplement including those that may not appear in the finished dietary ingredient or dietary supplement. Component includes ingredients and dietary ingredients as described in section 201(ff) of the act.

Consumer complaint means communication that contains any allegation, written or oral, expressing dissatisfaction with the quality of a dietary ingredient or a dietary supplement related to good manufacturing practices. Examples of product quality related to good manufacturing practices are: Foul odor, off taste, superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide,

mycotoxin, glass, lead), disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a dietary supplement container, improper packaging, or mislabeling. For the purposes of the regulations in this part, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices.

Contact surface means any surface that contacts a component, dietary ingredient, dietary supplement, and those surfaces from which drainage onto the component, dietary ingredient, dietary supplement, or onto surfaces that contact the component, dietary ingredient, or dietary supplement ordinarily occurs during the normal course of operations. Examples of contact surfaces include, but are not limited to, containers, utensils, tables, contact surfaces of equipment, and packaging.

Ingredient means any substance that is used in the manufacture of a dietary ingredient or dietary supplement that is intended to be present in the finished dietary ingredient or dietary supplement. An ingredient includes, but is not necessarily limited to, a dietary ingredient as described in section 201(ff) of the act.

Inprocess material means any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the manufacture of a dietary ingredient or dietary supplement.

Lot means a batch, or a specific identified portion of a batch intended to have uniform identity, purity, quality, strength, and composition; or, in the case of a dietary ingredient or dietary supplement produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is intended to have uniform identity, purity, quality, strength, and composition.

Microorganisms means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes, but is not limited to, species that:

(1) Have public health significance;

(2) Could cause a component, dietary ingredient, or dietary supplement to decompose;

(3) Indicate that the component, dietary ingredient, or dietary supplement is contaminated with filth; or

(4) Otherwise may cause the component, dietary ingredient, or dietary supplement to be adulterated.

Must is used to state mandatory requirements.

Pest means any objectionable insects or other animals including, but not limited to, birds, rodents, flies, mites, and larvae.

Physical plant means all or parts of a building or facility used for or in connection with manufacturing, packaging, or holding a dietary ingredient or dietary supplement.

Quality control means a planned and systematic operation or procedure for preventing a dietary ingredient or dietary supplement from being adulterated.

Quality control unit means any person or group that you designate to be responsible for quality control operations.

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

Reprocessing means using, in the manufacture of a dietary ingredient or a dietary supplement, clean, unadulterated components, dietary ingredients, or dietary supplements that have been previously removed from manufacturing for reasons other than insanitary conditions and that have been made suitable for use in the manufacture of a dietary ingredient or dietary supplement.

Sanitize means to adequately treat equipment, containers, utensils, or any other dietary product contact surface by applying cumulative heat or chemicals on cleaned food contact

surfaces that when evaluated for efficacy, yield a reduction of 5 logs, which is equal to 99.999 percent reduction, of representative disease microorganisms of public health significance and substantially reduce the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Theoretical yield means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or dietary supplement, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

Water activity (a_w) is a measure of the free moisture in a component, dietary ingredient, or dietary supplement and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

We means the United States Food and Drug Administration (FDA).

You means a person who manufactures, packages, or holds dietary ingredients or dietary supplements.

§ 111.5 Do other statutory provisions and regulations apply?

In addition to the regulations in this part, you must comply with other applicable statutory provisions and regulations under the act related to the manufacturing, packaging, or holding of dietary ingredients or dietary supplements.

§ 111.6 Exclusions.

The regulations in this part do not apply to a person engaged solely in activities related to the harvesting, storage, or distribution of raw agricultural commodities that will be incorporated into a dietary ingredient or dietary supplement by other persons.

4. Add new subpart B to part 111 to read as follows:

Subpart B--Personnel

111.10 What microbial contamination and hygiene requirements apply?

111.12 What personnel qualification requirements apply?

111.13 What supervisor requirements apply?

Subpart B--Personnel

§ 111.10 What microbial contamination and hygiene requirements apply?

(a) Microbial contamination. You must take measures to exclude from any operations any person who might be a source of microbial contamination of any material including components, dietary ingredients, dietary supplements, and contact surfaces used in the manufacture, packaging, or holding of a dietary ingredient or a dietary supplement. Such measures include, but are not limited to, the following:

(1) Excluding any person who, by medical examination or supervisory observation, is shown to have, or appears to have an

illness, open lesion, or any other abnormal source of microbial contamination, which may be expected to result in microbial contamination of components, dietary ingredients, dietary supplements, or contact surfaces, from working in any operations until the condition is corrected; and

(2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could contaminate any components, dietary ingredients, dietary supplements, or any contact surface.

(b) Hygienic practices. If you work in operations during which adulteration of the component, dietary ingredients, dietary supplement, or contact surface may occur, you must use hygienic practices to the extent necessary to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces. These hygienic practices include, but are not limited to:

(1) Wearing outer garments in a manner that protects against the contamination of components, dietary ingredients, dietary supplements, or any contact surface;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

(i) Before starting work; and

(ii) At any time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, dietary ingredients, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components, dietary ingredients, or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, dietary ingredients, dietary supplements, or contact surfaces;

(5) Maintaining gloves used in handling components, dietary ingredients, or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, dietary ingredients, or dietary supplements or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages and

using tobacco products in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and

(9) Taking any other precautions necessary to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

§ 111.12 What personnel qualification requirements apply?

(a) You must have qualified employees to manufacture, package, or hold dietary ingredients or dietary supplements; and

(b) Each person engaged in manufacturing, packaging, or holding must have the training and experience to perform the person's duties.

§ 111.13 What supervisor requirements apply?

(a) You must assign qualified personnel to supervise the manufacturing, packaging, or holding of dietary ingredients and dietary supplements.

(b) You and the supervisors you use must be qualified by training and experience to supervise.

5. Add new subpart C to part 111 to read as follows:

Subpart C--Physical Plant

111.15 What sanitation requirements apply to your physical

plant?

111.20 What design and construction requirements apply to your physical plant?

Subpart C--Physical Plant

§ 111.15 What sanitation requirements apply to your physical plant?

(a) Physical plant facilities. (1) You must maintain your physical plant in a clean and sanitary condition; and

(2) You must keep your physical plant in repair sufficient to prevent components, dietary ingredients, dietary supplements, or contact surfaces from becoming contaminated.

(b) Cleaning compounds, sanitizing agents, and pesticides. (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and safe and adequate under the conditions of use.

(2) You must not use or hold toxic materials in a physical plant in which contact surfaces, components, dietary ingredients, or dietary supplements are manufactured or exposed, unless those materials are necessary:

(i) To maintain clean and sanitary conditions;

(ii) For use in laboratory testing procedures;

(iii) For maintaining or operating the physical plant or equipment; or

(iv) For use in the plant's operations.

(3) You must identify and hold toxic cleaning compounds, sanitizing agents, pesticides, and pesticide chemicals in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

(c) Pest control. (1) You must not allow animals or pests in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination of components, dietary ingredients, dietary supplements, or contact surfaces;

(2) You must take effective measures to exclude pests from the physical plant and to protect against contamination of components, dietary ingredients, dietary supplements, and contact surfaces on the premises by pests; and

(3) You must not use insecticides, fumigants, fungicides, or rodenticides, unless you take precautions to protect against the contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

(d) Water supply. (1) You must provide water that is safe and of adequate sanitary quality, at suitable temperatures, and under pressure as needed, in all areas where water is necessary for:

(i) Manufacturing dietary ingredients or dietary supplements;

(ii) Making ice that comes in contact with components,

dietary ingredients, dietary supplements, or contact surfaces;

(iii) Cleaning any surface; and

(iv) Employee bathrooms and hand-washing facilities.

(2) Water that contacts components, dietary ingredients, dietary supplements, or any contact surface must at a minimum comply with the National Primary Drinking Water regulations prescribed by the Environmental Protection Agency under 40 CFR part 141 and any state and local government requirements;

(3) You must have documentation or otherwise be able to show that water that contacts components, dietary ingredients, dietary supplements, or any contact surface meets the requirements in paragraph (d)(2) of this section.

(e) Plumbing. The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from your physical plant;

(3) Avoid being a source of contamination to components, dietary ingredients, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition;

(4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal

operations release or discharge water or other liquid waste on the floor; and

(5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary ingredients or dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.

(f) Sewage disposal. You must dispose of sewage into an adequate sewage system or through other adequate means.

(g) Bathrooms. You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not become a potential source of contamination to components, dietary ingredients, dietary supplements, or contact surfaces. You must:

(1) Keep the bathrooms in good repair at all times;

(2) Provide self-closing doors; and

(3) Provide doors that do not open into areas where components, dietary ingredients, dietary supplements, or contact surfaces are exposed to airborne contamination except where alternate means have been taken to protect against contamination (such as double doors or positive airflow systems).

(h) Hand-washing facilities. You must provide hand-washing facilities that are adequate, convenient, and furnish running water at a suitable temperature. You must do this by providing:

(1) Hand-washing and, where appropriate, hand-sanitizing facilities at each location in your physical plant where good hygienic practices require employees to wash or to sanitize or both wash and sanitize their hands;

(2) Effective hand-cleaning and sanitizing preparations;

(3) Air driers, sanitary towel service, such as disposable paper towels, or other suitable drying devices;

(4) Devices or fixtures, such as water control valves, designed and constructed to protect against recontamination of clean, sanitized hands;

(5) Signs that are easy to understand and are posted throughout the physical plant that direct employees handling components, dietary ingredients, dietary supplements, or contact surfaces to wash and, where appropriate, to sanitize their hands before they start work, after each absence from their duty station, and when their hands may have become soiled or contaminated; and

(6) Trash bins that are constructed and maintained in a manner to protect against recontamination of hands and contamination of components, dietary ingredients, dietary supplements, or any contact surface.

(i) Trash disposal. You must convey, store, and dispose of trash to:

(1) Minimize the development of odor;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, dietary ingredients, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and

(4) Control hazardous waste to prevent contamination of components, dietary ingredients, dietary supplements, and contact surfaces.

(j) Sanitation supervisors. You must assign one or more employees to supervise overall sanitation. These supervisors must be qualified by training and experience to develop and supervise sanitation procedures.

§ 111.20 What design and construction requirements apply to your physical plant?

Any physical plant you use in the manufacture, packaging, or holding of dietary ingredients or dietary supplements must:

(a) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;

(b) Have adequate space for the orderly placement of equipment and holding materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components, dietary ingredients, and dietary supplements during manufacturing, packaging, or holding;

(c) Permit the use of proper precautions to reduce the

potential for mixups or contamination of components, dietary ingredients, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Your physical plant must have and you must use separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components, dietary ingredients, and dietary supplements during the following operations:

(1) Receiving, identifying, holding, and withholding from use, components, dietary ingredients, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, or holding of dietary ingredients and dietary supplements;

(2) Separating, as necessary, components, dietary ingredients, dietary supplements, packaging, and labels that are to be used from components, dietary ingredients, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection;

(3) Separating the manufacturing, packaging, and holding of different product types including, but not limited to, different types of dietary ingredients, dietary supplements and other foods, cosmetics, and pharmaceutical products;

(4) Performing laboratory analyses and holding laboratory supplies and samples;

(5) Cleaning and sanitizing contact surfaces;

(6) Packaging and label operations; and

(7) Holding dietary ingredients or dietary supplements.

(d) Be designed and constructed in a manner that prevents contamination of components, dietary ingredients, dietary supplements, or contact surfaces. The design and construction must include, but not be limited to:

(1) Floors, walls, and ceilings that are of smooth and hard surfaces that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, dietary ingredients, dietary supplements, or contact surfaces by dripping or condensate;

(3) Adequate ventilation or environmental control equipment such as air flow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate components, dietary ingredients, dietary supplements, or contact surfaces;

(4) Fans and other air-blowing equipment located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components,

dietary ingredients, dietary supplements, or contact surfaces;

(5) Equipment that controls temperature and humidity; and

(6) Aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces with clothing or personal contact.

(e) Provide adequate light in:

(1) All areas where components, dietary ingredients, or dietary supplements are examined, processed, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and bathrooms.

(f) Use safety-type light bulbs, fixtures, skylights, or other glass that is suspended over exposed components, dietary ingredients, or dietary supplements in any step of preparation, unless otherwise constructed in a manner that will protect against contamination of components, dietary ingredients, or dietary supplements in case of glass breakage.

(g) Provide protection by any effective means against contamination of components, dietary ingredients, and dietary supplements in bulk fermentation vessels, including consideration of:

(1) Use of protective coverings;

(2) Placement in areas where you can eliminate harborages for pests over and around the vessels;

(3) Placement in areas where you can check regularly for pests, pest infestation, filth or any other extraneous materials; and

(4) Use of skimming equipment.

(h) Use adequate screening or other protection against pests, where necessary.

6. Add new subpart D to part 111 to read as follows:

Subpart D--Equipment and Utensils

111.25 What requirements apply to the equipment and utensils you use?

111.30 What requirements apply to automatic, mechanical, or electronic equipment?

Subpart D--Equipment and Utensils

§ 111.25 What requirements apply to the equipment and utensils you use?

(a)(1) You must use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained. Equipment and utensils include, but are not limited to, the following:

(i) Equipment used to hold or convey;

(ii) Equipment used to measure;

(iii) Equipment using compressed air or gas;

(iv) Equipment used to carry out processes in closed pipes and vessels; and

(v) Equipment used in automatic, mechanical, or electronic systems.

(2) You must use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components, dietary ingredients, or dietary supplements with:

(i) Lubricants;

(ii) Fuel;

(iii) Coolants;

(iv) Metal or glass fragments;

(v) Filth or any other extraneous material;

(vi) Contaminated water; or

(vii) Any other contaminants.

(3) All equipment and utensils you use must be:

(i) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces;

(ii) Corrosion-resistant if the equipment or utensils contact components, dietary ingredients, or dietary supplements;

(iii) Made of nontoxic materials;

(iv) Designed and constructed to withstand the environment

of their intended use, the action of components, dietary ingredients, or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and

(v) Maintained to protect components, dietary ingredients, and dietary supplements from being contaminated by any source.

(4) Equipment and utensils you use must have seams that are smoothly bonded or maintained to minimize accumulation of component, dietary ingredient, or dietary supplement particles, dirt, filth, organic material, or any other extraneous materials or contaminants to minimize the opportunity for growth of microorganisms.

(5) Each freezer and cold storage compartment you use to hold components, dietary ingredients, or dietary supplements:

(i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that shows the temperature accurately within the compartment; and

(ii) Must have an automatic device for regulating temperature or an automatic alarm system to indicate a significant temperature change in a manual operation.

(6) Instruments or controls used in the manufacturing, packaging, or holding of a dietary ingredient or dietary supplement, including but not limited to, instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), water activity, or other conditions that

control or prevent the growth of microorganisms or other contamination must be:

(i) Accurate and precise;

(ii) Adequately maintained; and

(iii) Adequate in number for their designated uses.

(7) Compressed air or other gases you introduce mechanically into or onto a component, dietary ingredient, dietary supplement, or contact surface or that you use to clean any contact surface must be treated in such a way that the component, dietary ingredient, dietary supplement, or contact surface is not contaminated.

(b)(1) You must calibrate instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement.

(2) You must calibrate before first use; and

(i) As specified in writing by the manufacturer of the instrument and control, or

(ii) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.

(c) You must:

(1) Establish a written procedure for calibrating instruments and controls you use in manufacturing or testing a component, dietary ingredient, or dietary supplement and document that the written procedure was followed each time a calibration

is performed, or

(2) Document at the time of performance that the instrument and control calibration established in accordance with this section was performed.

(d) You must identify the following for calibrating instruments and controls in any written procedure or at the time of performance:

(1) The instrument or control calibrated;

(2) The date of calibration;

(3) The reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy;

(4) The calibration method used including appropriate limits for accuracy and precision of instruments and controls when calibrating;

(5) The calibration reading or readings found; and

(6) The recalibration method used if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and

(7) The initials of the person who performed the calibration.

(d) You must repair or replace instruments or controls that cannot be adjusted to agree with the reference standard.

(e)(1) You must maintain, clean, and sanitize as necessary,

all equipment, utensils, and any other contact surfaces that are used to manufacture, package, or hold components, dietary ingredients, or dietary supplements. Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.

(2) You must ensure that all contact surfaces used for manufacturing or holding of low-moisture components, dietary ingredients, or dietary supplements are in a dry and sanitary condition at the time of use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use.

(3) If you use wet processing during manufacturing, you must clean and sanitize all contact surfaces, as necessary, to protect against the introduction of microorganisms into components, dietary ingredients, or dietary supplements. When cleaning and sanitizing is necessary, you must clean and sanitize all contact surfaces before use and after any interruption during which the contact surface may have become contaminated. If you use contact surfaces in a continuous production operation or in back-to-back operations involving different batches of the same dietary ingredient or dietary supplement, you must clean and sanitize the contact surfaces as necessary.

(4) You must clean surfaces that do not touch components, dietary ingredients, or dietary supplements as frequently as

necessary to protect against contaminating components, dietary ingredients, or dietary supplements.

(5) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be:

(i) Stored in appropriate containers; and

(ii) Handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary ingredients, dietary supplements, or any contact surface.

(6) Cleaning compounds and sanitizing agents must be adequate for intended use and safe under condition of use;

(7) You must store cleaned and sanitized portable equipment and utensils that have contact surfaces in a location and manner that protects them from contamination.

(f) You must keep calibration records as required by this section in accordance with § 111.125.

§ 111.30 <u>What requirements apply to automatic, mechanical, or electronic equipment</u>?

(a) When you use automatic, mechanical, or electronic equipment to manufacture, package, label, and hold a dietary ingredient or dietary supplement, you must:

(1) Design or select equipment to ensure that dietary ingredient or dietary supplement specifications are consistently achieved and

(2) Determine the suitability of your equipment by ensuring

that your equipment is capable of operating satisfactorily within the operating limits required by the process.

(b) For any automatic, mechanical, or electronic equipment you use, you must:

(1) Routinely calibrate, inspect, or check to ensure proper performance. Your quality control unit must approve these calibrations, inspections, or checks;

(2) Make and keep written records of equipment calibrations, inspections, or checks;

(3) Establish and use appropriate controls, to ensure that your quality control unit approves changes in the master manufacturing record, batch control records, packaging operations and label operations, or changes to other operations related to the equipment that you use and that only authorized personnel institute the changes;

(4) Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. These controls must be approved by your quality control unit; and

(5) Make and keep backup file(s) of software programs and of data entered into your computer system. Your backup file (e.g., a hard copy of data you have entered, diskettes, tapes, microfilm, or compact disks) must be an exact and complete record of the data you entered. You must keep your backup software programs and data secure from alterations, inadvertent erasures,

or loss.

(c) You must keep automatic, mechanical, or electronic equipment records required by this section in accordance with § 111.125.

§ 111.50 [Redesignated as § 111.72 and Amended]

7. Redesignate § 111.50 as § 111.72 and transfer it to a new subpart E, Production and Process Controls, and revise the section heading to read as follows:

§ 111.72 What requirements apply to packaging of iron-containing dietary supplements?

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8. Add §§ 111.35 through 111.70 and § 111.74 to newly added subpart E to read as follows:

§ 111.35 What production and process controls must you use?

(a) You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary ingredients and dietary supplements.

(b) Your production and in-process control system must be designed to ensure that the dietary ingredient or dietary supplement is manufactured, packaged, and held in a manner that will prevent adulteration of the dietary ingredient or dietary supplement. The production and in-process control system must include all requirements of this subpart and must be reviewed and

approved by the quality control unit.

(c) You must use a quality control unit in your manufacturing, packaging, and label operations for producing the dietary ingredient or dietary supplement to ensure that these operations are performed in a manner that prevents adulteration and ensures that the dietary ingredient or dietary supplement meets specifications for identity, purity, quality, strength, and composition.

(d) Any substance, other than a "dietary ingredient" within the meaning of section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the act), the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of the dietary ingredient or dietary supplement must be:

(1) Authorized for use as a food additive under section 409 of the act; or

(2) Authorized by a prior sanction consistent with § 170.3(l) of this chapter; or

(3) If used as a color additive, subject to a listing that, by the terms of that listing, includes the use in a dietary supplement; or

(4) Generally recognized as safe (GRAS) for use in a dietary ingredient or dietary supplement. Any claim that a substance is GRAS, other than a dietary ingredient within the

meaning of section 201(ff) of the act, must be supported by a citation to the agency's regulations or by an explanation for why there is general recognition of safety of the use of the substance in a dietary ingredient or dietary supplement; and

(5) Must comply with all other applicable statutory and regulatory requirements under the act.

(e) You must establish a specification for any point, step, or stage in the manufacturing process where control is necessary to prevent adulteration. Specifications must be established for:

(1) The identity, purity, quality, strength, and composition of components, dietary ingredients, or dietary supplements that you receive;

(2) The in-process controls in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;

(3) The identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement that you manufacture; and

(4) The dietary ingredient or dietary supplement labels and the packaging that may come in contact with dietary ingredients and dietary supplements. The packaging must be safe and suitable for its intended use and comply with all other applicable statutory and regulatory requirements under the act and must not

be reactive or absorptive so as to affect the safety of the dietary ingredient and dietary supplement.

(f) You must monitor the in-process control points, steps, or stages to ensure that specifications established under paragraph (e) of this section are met and to detect any unanticipated occurrence that may result in adulteration;

(g) You must ensure, through testing or examination, that each specification that you established under paragraph (e) of this section is met. Specific testing requirements are as follows:

(1) You must test each finished batch of the dietary ingredient or dietary supplement produced before releasing for distribution to determine whether established specifications for identity, purity, quality, strength, and composition are met, provided that there are scientifically valid analytical methods available to conduct such testing.

(2) For any specification for identity, purity, quality, strength, or composition for which you document cannot be tested on the finished batch of a dietary ingredient or dietary supplement, because there is no scientifically valid analytical method available for such testing, then you must:

(i) Perform testing on each shipment lot of components, dietary ingredients or dietary supplements received to determine whether such specification is met; and

(ii) Perform testing in-process in accordance with the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements; and

(3) Your quality control unit must determine when finished batch testing cannot be completed for any specification on the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements.

(h) You must use an appropriate test or examination to determine whether your specifications are met. An appropriate test is one that is a scientifically valid analytical method.

(i) You must:

(1) Establish corrective action plans for use when an established specification is not met;

(2) Review the results of the monitoring required by this section and conduct a material review of any component, dietary ingredient, dietary supplement, packaging or label for which you establish a specification that is not met, or any unanticipated occurrence that adulterates or could result in adulteration of the component, dietary ingredient, dietary supplement, packaging, or label; and

(3) Make a material disposition decision for any component, dietary ingredient, dietary supplement, packaging, or label:

(i) If a component, dietary ingredient, dietary supplement,

packaging, or label fails to meet specifications;

(ii) If any step established in the master manufacturing record is not completed;

(iii) If there is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label;

(iv) If calibration of an instrument or control suggests a problem that may have caused batches of a dietary ingredient or dietary supplement to become adulterated; or

(v) If a dietary ingredient or dietary supplement is returned.

(4) For any deviation or unanticipated occurrence which resulted in or could lead to adulteration of the component, dietary ingredient, dietary supplement, packaging, or label:

(i) You must reject the component, dietary ingredient, dietary supplement, packaging, or label, unless the quality control unit determines that in-process adjustments are possible to correct the deviation or occurrence;

(ii) You must not reprocess a rejected component, dietary ingredient, or dietary supplement unless approved by the quality control unit; and

(iii) You must not reprocess any component, dietary ingredient or dietary supplement if it is rejected because of

contamination with microorganisms or other contaminants, such as heavy metals;

(5) Have your quality control unit review and approve any material review and disposition decision described in paragraphs (i)(2) and (i)(3) of this section.

(j) The person who conducts the material review and makes the disposition decision must, at the time of performance, document every material review and disposition decision in paragraph (i) of this section. The documentation must be included in the appropriate batch production record and must:

(1) Identify the specific deviation from the specification or the unanticipated occurrence;

(2) Describe your investigation into the cause of the deviation from the specification or the unanticipated occurrence;

(3) Evaluate whether or not the deviation from the specification or unanticipated occurrence has resulted in or could lead to adulteration;

(4) Identify the action(s) taken to correct and prevent a recurrence of the deviation or the unanticipated occurrence; and

(5) Discuss what you did with the component, dietary ingredient, dietary supplement, packaging, or label.

(k) You must test or examine components, dietary ingredients, and dietary supplements for those types of contamination that may adulterate or may lead to adulteration.

You must use an appropriate scientifically valid method for the test or examination. The types of contamination include, but are not limited to, the following:

(1) Filth, insects, or other extraneous material;

(2) Microorganisms; and

(3) Toxic substances.

(l) Tests in accordance with this section must include at least one of the following:

(1) Gross organoleptic analysis;

(2) Microscopic analysis;

(3) Chemical analysis; or

(4) Other appropriate test.

(m) You must record results of all testing and examinations performed in accordance with this section. If a test or examination is performed on a batch production you must record the test or examination result in the batch production record in accordance with § 111.50(c)(10). Your records must document whether the testing and examination demonstrates that specifications are met.

(n) For any specification that is not met, you must conduct a material review and disposition decision under paragraph (i) of this section.

(o) You must make and retain records, in accordance with § 111.125, to ensure that you follow the requirements of this

section. The records must include, but are not limited to:

(1) The specifications established;

(2) The actual results obtained during the monitoring operation;

(3) Any deviation from specifications and any unanticipated occurrences;

(4) Any corrective actions taken;

(5) The disposition decisions and followup; and

(6) The identity of the individual qualified by training and experience who investigated any deviation from specifications or unanticipated occurrence and the identity of the individual from the quality control unit who reviewed the results of that investigation.

§ 111.37 What requirements apply to quality control?

(a) You must use a quality control unit to ensure that your manufacturing, packaging, label, and holding operations in the production of dietary ingredients and dietary supplements are performed in a manner that prevents adulteration and misbranding, including ensuring that dietary ingredients and dietary supplements meet specifications for identity, purity, quality, strength, and composition.

(b) Your quality control unit must do the following:

(1) Approve or reject all processes, specifications, controls, tests, and examinations, and deviations from or

modifications to them, that may affect the identity, purity, quality, strength, and composition of a dietary ingredient or dietary supplement;

(2) Determine whether all components, dietary ingredients, dietary supplements, packaging, and labels conform to specifications;

(3) Approve or reject all components, dietary ingredients, dietary supplements, packaging, and labels;

(4) Review and approve all master manufacturing records and all modifications to the master manufacturing records;

(5) Review and approve all batch production-related records which include, but are not limited to, cross referencing receiving and batch production records, approval of a material review and disposition decision, approval for reprocessing, and approval for releasing for distribution;

(6) Review and approve all processes for calibrating instruments or controls;

(7) Review all records for calibration of instruments, apparatus, gauges, and recording devices;

(8) Review all records for equipment calibrations, inspections, and checks;

(9) Review and approve all laboratory control processes, and testing results;

(10) Review and approve all packaging and label records

which include, but are not limited to, cross-referencing receiving and batch production records, approval for repackaging and relabeling, and approval for releasing for distribution;

(11) Collect representative samples of:

(i) Each shipment lot of components, dietary ingredients, dietary supplements, packaging, and labels received to determine whether the component, dietary ingredient, dietary supplement, packaging, or labels meet specifications;

(ii) Inprocess materials at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, quality, strength, and composition of dietary ingredients or dietary supplements;

(iii) Each batch of dietary ingredient or dietary supplement manufactured to determine, before releasing for distribution, whether the dietary ingredient or dietary supplement meets its specifications for identity, purity, quality, strength, and composition; and

(iv) Each batch of packaged and labeled dietary ingredients or dietary supplements to determine that you used the packaging specified in the master manufacturing record and applied the label specified in the master manufacturing record.

(12) Keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations including, but

not limited to, consumer complaint investigations to determine, for example, whether the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. The reserve samples must:

(i) Be identified with the batch or lot number; and

(ii) Consist of at least twice the quantity necessary for tests.

(13) Perform appropriate tests and examinations of:

(i) Components, dietary ingredients, dietary supplements, packaging, and labels received to ensure that they meet specifications;

(ii) Dietary ingredient and dietary supplement batch production at points, steps, or stages identified in the master manufacturing record where control is necessary to prevent adulteration;

(iii) Dietary ingredients and dietary supplements that you manufacture to ensure that they meet specifications; and

(iv) Packaged and labeled dietary ingredients and dietary supplements to ensure that you used the packaging specified in the master manufacturing record and you applied the label specified in the master manufacturing record.

(14) Review and approve all material review and disposition decisions; and

(15) Approve the reprocessing or distribution of returned dietary ingredients or dietary supplements.

(c) Your quality control unit must establish and maintain written documentation at the time of performance that it performed the review, approval, or rejection requirements of this section by recording the following:

(1) Date the required review, approval, or rejection was performed; and

(2) Signature of the person performing the requirement.

(d) You must keep quality control records in accordance with § 111.125.

§ 111.40 What requirements apply to components, dietary ingredients, dietary supplements, packaging, and labels you receive?

(a) For components, dietary ingredients, or dietary supplements you receive, you must:

(1) Visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition has resulted in contamination or deterioration of the components, dietary ingredients, or dietary supplement;

(2) Visually examine the suppliers invoice, guarantee, or certification to ensure that the components, dietary ingredients, or dietary supplements are consistent with your purchase order

and perform testing, as needed, to determine whether specifications are met.

(3) Quarantine components, dietary ingredients, or dietary supplements until your quality control unit reviews the suppliers invoice, guarantee, or certification and performs testing, as needed, of a representative sample to determine that specifications are met. If specifications are not met, you must conduct a material review and make a disposition decision. Your quality control unit must approve and release the components, dietary ingredients, and dietary supplements from quarantine before you use them;

(4) Identify each lot of components, dietary ingredients, or dietary supplements in a shipment in a manner that allows you to trace the shipment to the supplier, the date received, the name of the component or dietary supplement, and the status (e.g., quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received; and

(5) Hold components, dietary ingredients, or dietary supplements under conditions that will protect against contamination, deterioration, and avoid mixups.

(b) For packaging and labels you receive, you must:

(1) Visually examine each container or grouping of containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition has resulted in contamination or deterioration of the packaging and labels;

(2) Quarantine packaging and labels until your quality control unit tests or examines a representative sample to determine that specifications are met. You must conduct at least a visual identification on the containers and closures. If specifications are not met, you must conduct a material review and make a disposition decision. Your quality control unit must approve and release packaging and labels from quarantine before you use them;

(3) Identify each shipment lot of packaging and labels in a manner that allows you to trace the shipment lot to the supplier, the date received, the name of the packaging and label and the status (e.g., quarantined, approved, or rejected) and to trace the shipment lot to the dietary ingredient or dietary supplement manufactured and distributed. You must use this unique identifier whenever you record the disposition of each shipment lot received; and

(4) Hold packaging and labels under conditions that will protect against contamination, deterioration, and avoid mixups.

(c)(1) The person who performs the component, dietary

ingredient, dietary supplement, packaging, or label requirements of this section must document, at the time of performance, that the requirements were followed. The documentation must include, but not be limited to:

(i) The date that the components, dietary ingredients, dietary supplements, packaging, or labels were received;

(ii) The signature of the person performing the requirement;

(iii) Any test results; and

(iv) Any material review and disposition decision you conducted in accordance with § 111.35(i) and disposition of any rejected material under § 111.74.

(2) You must keep component, dietary supplement, packaging, and label receiving records in accordance with § 111.125.

§ 111.45 What requirements apply to establishing a master manufacturing record?

(a) You must prepare and follow a written master manufacturing record for each type of dietary ingredient or dietary supplement that you manufacture and for each batch size to ensure uniformity from batch to batch. The master manufacturing record must:

(1) Identify specifications for the points, steps, or stages in the manufacturing process where control is necessary to prevent adulteration; and

(2) Establish controls and procedures to ensure that each batch of dietary ingredient or dietary supplement manufactured meets those specifications.

(b) The master manufacturing record must include the following information:

(1) The name of the dietary ingredient or dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size;

(2) A complete list of components to be used;

(3) An accurate statement of the weight or measure of each component to be used;

(4) The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement in compliance with section 403(s) of the Federal Food, Drug, and Cosmetic Act;

(5) A statement that explains any intentional excess amount of a dietary ingredient;

(6) A statement of theoretical yield of a manufactured dietary ingredient or dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to prevent adulteration, and the expected yield when you finish manufacturing the dietary ingredient or dietary

supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is performed and material review is conducted and disposition decision is made;

(7) A description of packaging and a copy of the label to be used; and

(8) Written instructions including, but not limited to, the following:

(i) Specifications for each point, step, or stage in manufacturing the dietary ingredient or dietary supplement necessary to prevent adulteration;

(ii) Sampling and testing procedures;

(iii) Specific actions necessary to perform and verify points, steps, or stages, necessary to meet specifications and otherwise prevent adulteration, including, but not limited to, one person weighing or measuring a component and another person verifying the weight or measure and one person adding the component and another person verifying the addition;

(iv) Special notations and precautions to be followed; and

(v) Corrective action plans for use when a specification is not met.

(c) You must have the quality control unit review and approve each master manufacturing record and any modifications to a master manufacturing record.

(d) You must keep master manufacturing records in accordance with § 111.125.

§ 111.50 What requirements apply to establishing a batch production record?

(a) You must prepare a batch production record every time you manufacture a batch of a dietary ingredient or dietary supplement and the batch production record must include complete information relating to the production and control of each batch.

(b) Your batch production record must accurately follow the appropriate master manufacturing record and you must perform each step in producing the batch.

(c) The batch production record must include, but is not limited to, the following information:

(1) The batch, lot, or control number;

(2) Documentation at the time of performance, showing the date on which each step of the master manufacturing record was performed, and the initials of the persons performing each step, including but not limited to:

(i) The person responsible for weighing or measuring each component used in the batch; and

(ii) The person responsible for adding the component to the batch.

(3) The identity of equipment and processing lines used in producing the batch;

(4) The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch;

(5) The shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used;

(6) The identity and weight or measure of each component used;

(7) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the weight or measure of each component used in the batch;

(8) The initials at the time of performance or at the completion of the batch of the person responsible for verifying the addition of components to the batch;

(9) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(10) The actual test results for any testing performed during the batch production;

(11) Documentation that the dietary ingredient and dietary supplement meets specifications;

(12) Copies of all container labels used and the results of examinations conducted during the label operation to ensure that the containers have the correct label;

(13) Any documented material review and disposition decision in accordance with § 111.35(j); and

(14) Signature of the quality control unit to document batch production record review and any approval for reprocessing or repackaging,

(d) The quality control unit must review in accordance with § 111.37(b)(5) the batch production record established in paragraph (c) of this section.

(1) If a batch deviates from the master manufacturing record, including any deviation from specifications, the quality control unit must conduct a material review and make a disposition decision and record any decision in the batch production record.

(2) The quality control unit must not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet all specifications.

(e) The quality control unit must document in accordance with § 111.37(c) the review performed in accordance with paragraph (d) of this section and it must be documented at the time of performance. The review and documentation must include, but is not limited to, the following:

(1) Review of component, dietary ingredient, and dietary supplement receiving records including review of testing and examination results;

(2) Identification of any deviation from the master manufacturing record that may have caused a batch or any of its components to fail to meet specifications identified in the master production record;

(3) Records of investigations, conclusions, and corrective actions performed in accordance with paragraph (d) of this section; and

(4) The identity of the person qualified by training and experience who performed the investigation in accordance with paragraph (d) of this section.

(f) You must not reprocess a batch that deviates from the master manufacturing record unless approved by the quality control unit. You must not reprocess a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metals;

(g) Any batch of dietary ingredient or dietary supplement that is reprocessed must meet all specifications for the batch of dietary ingredient or dietary supplement and be evaluated and approved by the quality control unit before releasing for distribution. The results of the reevaluation by the quality control unit must be documented in the batch production record; and

(h) You must collect representative reserve samples of each

batch of dietary ingredient or dietary supplement and keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine whether, for example, the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition.

(i) You must keep batch production records in accordance with § 111.125.

§ 111.60 What requirements apply to laboratory operations?

(a) You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine that components, dietary ingredients, and dietary supplements received meet specifications; that specifications are met during in-process, as specified in the master manufacturing record; and that dietary ingredients and dietary supplements manufactured meet specifications.

(b)(1) You must establish and follow laboratory control processes that are approved by the quality control unit. Laboratory control processes must include, but are not limited to, the following:

(i) Use of criteria for selecting appropriate examination and testing methods;

(ii) Use of criteria for establishing appropriate specifications; and

(iii) Use of sampling plans for obtaining representative samples of:

(A) Components, dietary ingredients, and dietary supplements received to determine whether specifications are met;

(B) In-process materials during the batch manufacturing when testing or examination is required in the master manufacturing record;

(C) Each batch of dietary ingredient or dietary supplement manufactured to determine that the dietary ingredient or dietary supplement meets specifications;

(D) Packaging and labels received to determine that the materials meet specifications; and

(E) Each batch of packaged and labeled dietary ingredients or dietary supplements to ensure that the label specified in the master manufacturing record has been applied.

(iv) Use of criteria for selecting standard reference materials used in performing tests and examinations;

(v) Use of appropriate test method validations; and

(vi) Use of test methods and examinations in accordance with established criteria.

(2) The person who conducts the testing and examination at the time of performance, must document that laboratory

methodology established in accordance with this section is followed. The documentation must include the testing and examination results.

(3) You must keep laboratory examination and testing records in accordance with § 111.125.

(c) You must verify that the laboratory examination and testing methodologies are appropriate for their intended use.

(d) You must identify and use the appropriate validated testing method for each established specification for which testing is required to determine whether the specification is met.

§ 111.65 What requirements apply to manufacturing operations?

(a) You must design or select manufacturing processes to ensure that dietary ingredient or dietary supplement specifications are consistently achieved.

(b) You must conduct all manufacturing operations in accordance with adequate sanitation principles.

(c) You must take all the necessary precautions during the manufacture of a dietary ingredient or dietary supplement to prevent contamination of components, dietary ingredients, or dietary supplements. These precautions include, but are not limited to:

(1) Performing manufacturing operations under conditions and controls that protect against the potential for growth of

microorganisms and the potential for contamination;

(2) Washing or cleaning components that contain soil or other contaminants;

(3) Using water that meets the National Primary Drinking Water regulations or, where necessary, higher sanitary quality and that complies with all applicable Federal, State, and local regulations for water that is used in the manufacturing operation. If you reuse water that was used to wash components to remove soil or contaminants, the reused water must be safe and of adequate sanitary quality so that it does not become a source of contamination;

(4) Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components, dietary ingredients, and dietary supplements;

(5) Sterilizing, pasteurizing, freezing, refrigerating, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (a_w), or using any other effective means to remove, destroy, or prevent the growth of microorganisms and prevent decomposition;

(6) Holding components, dietary ingredients, and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents the components, dietary ingredients, and dietary supplements from becoming adulterated;

(7) Identifying and holding any components, dietary ingredients, or dietary supplements, for which a material review and disposition decision is required, in a manner that protects the components, dietary ingredients, or dietary supplements against contamination and mixups;

(8) Performing mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary ingredients or dietary supplements against contamination. Such steps must include consideration of:

(i) Cleaning and sanitizing contact surfaces;

(ii) Using temperature controls; and

(iii) Using time controls.

(9) Using effective measures to protect against the inclusion of metal or other foreign material in components, dietary ingredients, or dietary supplements. Compliance with this requirement must include consideration of the use of:

(i) Filters or strainers;

(ii) Traps;

(iii) Magnets; or

(iv) Electronic metal detectors.

(10) Segregating and identifying all containers for a specific batch of dietary ingredients or dietary supplements to identify their contents and, where necessary, the phase of

manufacturing; and

(11) Identifying all processing lines and major equipment used during manufacturing to indicate their contents including the name of the dietary ingredient or dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing.

(d) You must conduct a material review and make a disposition decision in accordance with § 111.35(i) for any component, dietary ingredient, or dietary supplement that fails to meet specifications or that is or may be adulterated. If the material review and disposition decision allows you to reprocess the component, dietary ingredient, or dietary supplement, you must retest or reexamine the component, dietary ingredient, or dietary supplement to ensure that it meets specifications and is approved by the quality control unit.

§ 111.70 What requirements apply to packaging and label operations?

(a) You must take necessary actions to ensure that each packaging container for holding dietary ingredients or dietary supplements meets specifications so that the condition of the packaging container will not contaminate your dietary ingredients or dietary supplements nor cause them to deteriorate;

(b) You must fill, assemble, package, and perform other related operations in a way that protects your dietary

ingredients or dietary supplements against adulteration and misbranding. You must do this using any effective means, including but not limited to, the following:

(1) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary ingredient or dietary supplement containers, as appropriate;

(2) Protecting manufactured dietary ingredients and dietary supplements from contamination, particularly airborne contamination;

(3) Using sanitary handling procedures;

(4) Establishing physical or spatial separation of packaging and labels from operations on other dietary ingredients and dietary supplements to prevent mixups;

(5) Identifying, by any effective means, filled dietary ingredient or dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;

(6) Identifying the dietary ingredient or dietary supplement with a batch, lot, or control number that can be used to determine the manufacturing history and control of the batch;

(7) Examining a representative sample of each batch of the packaged and labeled dietary ingredient or dietary supplement to ensure that the dietary ingredient or dietary supplement meets specifications and that the label specified in the master

manufacturing record has been applied; and

(8) Suitably disposing of labels and other packaging for dietary ingredients or dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

(c) You must conduct a material review and make a disposition decision of any packaged and labeled dietary ingredients or dietary supplements that do not meet specifications.

(d) You must only repackage or relabel dietary ingredients or dietary supplements after the quality control unit has approved and documented such repackaging or relabeling.

(e) You must retest or reexamine any repackaged or relabeled dietary ingredients or dietary supplements. They must meet all specifications and the quality control unit must approve or reject their release for distribution.

(f)(1) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies; and

(2) You must examine, before packaging operations, packaging and labels for each batch of dietary ingredient or dietary supplement to ensure that the label and packaging conform to the master manufacturing record.

(g) The person that performs the requirements of this

section must document at the time of performance that the requirements are performed including, but not limited to, documentation in the batch production record of:

(1) The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use;

(2) The examination conducted in accordance with paragraph (b)(7) of this section;

(3) The conclusions you reached from retests conducted in accordance with paragraph (e) of this section; and

(4) Any material reviews and disposition decisions for packaging and labels.

(h) You must keep packaging and label operations records required under this section in accordance with § 111.125.

§ 111.74 What requirements apply to rejected components, dietary ingredients, dietary supplements, packaging, and labels?

You must clearly identify, hold, and control under a quarantine system any component, dietary ingredient, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or label operations.

9. Add subpart F to part 111 to read as follows:

Subpart F--Holding and Distributing

Subpart F--Holding and Distributing

§ 111.80 What requirements apply to holding components, dietary ingredients, dietary supplements, packaging, and labels?

(a) You must hold components, dietary ingredients, and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, quality, strength, and composition of the components, dietary ingredients, and dietary supplements are not affected.

(b) You must hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected.

(c) You must hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels.

§ 111.82 What requirements apply to holding in-process material?

(a) You must identify and hold in-process material under conditions that will protect them against mixup, contamination, and deterioration.

(b) You must hold in-process material under appropriate conditions of temperature, humidity, and light.

§ 111.83 What requirements apply to holding reserve samples of components, dietary ingredients, and dietary supplements?

(a) For any reserve samples of components or dietary ingredients you collect, you must hold such reserve samples in a manner that protects against contamination and deterioration.

(b) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes, but is not limited to:

(1) Holding the reserve samples under conditions of use recommended or suggested in the label of the dietary supplement and, if no conditions of use are recommended or suggested in the label, then under ordinary conditions of use; and

(2) Using the same container-closure system in which the dietary supplement is marketed or in one that provides the same level of protection against contamination or deterioration.

§ 111.85 What requirements apply to returned dietary ingredients or dietary supplements?

(a) You must identify and quarantine returned dietary ingredients or dietary supplements until the quality control unit conducts a material review and makes a disposition decision.

(b) You must not salvage returned dietary ingredients and dietary supplements, unless:

(1) Evidence from their packaging (or, if possible, an inspection of the premises where the dietary ingredients and dietary supplements were held) indicates that the dietary ingredients and dietary supplements were not subjected to improper storage conditions; and

(2) Tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition.

(c) You must destroy or suitably dispose of the returned dietary ingredients or dietary supplements if such dietary ingredients or dietary supplements do not meet specifications for identity, purity, quality, strength, and composition, unless the

quality control unit conducts a material review and makes a disposition decision to allow reprocessing.

(d) If the reason for a dietary ingredient or a dietary supplement being returned implicates associated batches, you must conduct an investigation of your manufacturing processes and those other batches to determine compliance with specifications.

(e) You must establish and keep records for this section on the material review and disposition decision and any testing conducted to determine compliance with established specifications in the master manufacturing record for the type of dietary ingredient or dietary supplement that was returned.

(f) You must keep returned dietary ingredient and dietary supplement records in accordance with § 111.125.

§ 111.90 What requirements apply to distributing dietary ingredients or dietary supplements?

Distribution of dietary ingredients and dietary supplements must be under conditions that will protect the dietary ingredients and dietary supplements against contamination and deterioration.

10. Add subpart G to part 111 to read as follows:

Subpart G--Consumer Complaints

§ 111.95 What requirements apply to consumer complaints?

(a) A qualified person must review all consumer complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury.

(b) Your quality control unit must review all consumer complaints involving the possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint.

(c) Your quality control unit must investigate a consumer complaint when there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event.

(d) Your quality control unit's investigation of a consumer complaint must include the batch records associated with the dietary ingredient or dietary supplement involved in the consumer complaint. Your quality control unit must extend the investigation to other batches of dietary ingredients or dietary

supplements that may have been associated with an adverse event.

(e) You must make and keep a written record of every consumer complaint that is related to good manufacturing practices. For the purposes of the regulations in this part, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices. The consumer complaint written record must include, but is not limited to, the following:

(1) The name and description of the dietary ingredient or dietary supplement;

(2) The batch or lot number of the dietary supplement, if available;

(3) The name of the complainant, if available;

(4) The nature of the complaint including how the consumer used the product;

(5) The reply to the complainant, if any; and

(6) Findings of the investigation and followup action taken when an investigation is performed.

(f)(1) The person who performs the requirements in accordance with this section must document at the time of performance that the requirement was performed.

(2) You must keep consumer complaint records in accordance with § 111.125.

11. Add subpart H to part 111 to read as follows:

Subpart H--Records and Recordkeeping

§ 111.125 What requirements apply to recordkeeping?

(a) You must keep written records required by this part for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records.

(b) Records required under this part must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA. All electronic records must comply with part 11 of this chapter.

(c) You must have all records required under this part, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when

requested.

12. Part 112 is added to read as follows:

PART 112--RESTRICTIONS FOR SUBSTANCES USED IN DIETARY SUPPLEMENTS

Subpart A--General Provisions [Reserved]

Subpart B--New Dietary Ingredients [Reserved]

Subpart C--Restricted Dietary Ingredients [Reserved]

Authority: 21 U.S.C. 321, 342, 343, 371.

Date: January 29, 2003

Mark B. McClellan,

Commissioner of Food and Drugs.

Date: JAN 29 2003

Tommy G. Thompson,

Secretary of Health and Human Services.

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