

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

(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.