

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

Sec.

111.10 What microbial contamination and hygiene requirements apply?

111.12 What personnel qualification requirements apply?