

**APPENDIX
ONE**

111.3 WHAT DEFINITIONS APPLY TO THIS PART?

- AER:** Adverse Event Report.
- AOAC:** Association of Official Analytical Chemists; sanctioned officially validated methods.
- Actual Yield:** The quantity that is actually produced at any appropriate step of manufacture or packaging of a particular dietary ingredient or dietary supplement.
- Adulterate:** A component, dietary ingredient, or dietary supplement is adulterated if:
- (a) It presents a significant risk or illness or injury under conditions of use described in the labeling, or if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.
 - (b) It is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that the dietary ingredient does not present a significant or unreasonable risk of illness or injury.
 - (c) It is or contains a dietary ingredient that renders it adulterated under section 402(a)(1) of the act under the conditions of use recommended or suggested in the labeling. (Section 402(a)(1) of the act declares a food to be adulterated if it contains substances that are poisonous or deleterious substance that may render it injurious to health.)
 - (d) Additionally, section 301(a) of the act prohibits the introduction of adulterated food into interstate commerce.
- ANPRM:** Advance notice of proposed rule making.
- AHPA:** American Herbal Products Association.
- Batch:** 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.
- CBER:** FDA Center for Biologics Evaluation and Research.
- CFR:** Code of Federal Regulations.

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- CGMP:** Current good manufacturing practices are FDA approved methods for *manufacturing drug ingredients, drug substances, drugs, drug holding, drug packaging, drug labeling, drug analytical methods, and dietary ingredients, dietary supplements, dietary intermediate holding, dietary packaging, dietary labeling and dietary analytical methods.*
- Component:** A substance intended for use in the manufacture of dietary ingredient or dietary supplement including those that may not appear in the finished dietary ingredient or dietary supplement. Component includes ingredients and dietary supplements as described in section 201(ff) of the Act.
- Composition:** The intended mix of product and product-related substances.
- Consumer Complaint:** Means any communication that contains allegation, written or oral, expressing dissatisfaction with the quality of a dietary ingredient or a dietary supplement related to 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, dietary supplement, ordinarily occurs during the normal course of operations.
- DAL:** Specific defect action levels established for some food ingredients
- DSHEA:** Dietary Supplement, Health, and Education Act, Public Law 103-147, October 25, 1994; Provides in part that the Secretary of Health and Human Services may by regulation prescribe good manufacturing practices for dietary supplements.
- FAC:** Food advisory committee.
- FDA:** The United States Food and Drug Administration.
- Food Code:** An FDA compendium that guides retail outlets, such as restaurants and grocery stores and institutions such as nursing homes in how to prevent foodborne illnesses from food that is consumed without further processing by the consumer,
- GRAS:** Generally recognized as safe (GRAS) for use in a dietary ingredient or dietary supplement.
- HACCP:** Hazard Analysis and Critical Control Point; procedures for the safe and sanitary processing and importing of juice. 21 CFR Part 106; infant formula 21 CFR Part 113; fish and fishery products 21 CFR Part 123.
- Identity:** Shown to be what is represented on the label.

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- 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.
- In-process 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 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.
 - (4) May cause the component, dietary ingredient, or dietary supplement to be adulterated.
- Must:** A term used to convey mandatory requirements.
- NNFA:** National Nutritional Foods Association, 3931 MacAuthur Boulevard, Suite 101, Newport Beach, California 92660-1999.
- NPDW:** National Primary Drinking Water; An Environmental Protection Agency (EPA) regulation found in 40 CFR part 141. Also in 21 CFR part 111.15(d) proposal requiring use of water that is of safe and sanitary quality in all aspects of your operation where if not used would result in contamination and adulteration of your dietary ingredient or dietary supplement.
- PEST:** Any objectionable insects or other animals including, but not limited to, birds, rodents, flies, mites, and larvae.
- PHYSICAL PLANT:** All or parts of a building or facility used for or in connection with manufacturing, packaging, or holding a dietary ingredient or dietary supplement.
- Purity:** Does not contain impurities and is the desired product.

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Quality (Product): A specific entity has the desired identity, purity, and strength for its intended purpose.

QUALITY CONTROL: A planned and systematic operation or procedure for preventing a dietary ingredient or dietary supplement from being adulterated.

QUALITY CONTROL UNIT: Any person or group that you designate to be responsible for quality control operations.

REPRESENTATIVE SAMPLE: 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: To adequately treat equipment, containers, utensils, dietary ingredient or dietary supplement or final product, or 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. Implications of this FDA "Food Code" definition is to substantially reduce the numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Strength: A product is the concentration, that is the amount per unit of use intended.

THEORETICAL YIELD: 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): 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.

USDA: United States Department of Agriculture.

USP: United States Pharmacopeia.