

## § 111.5

previously removed from manufacturing and that have been made suitable for use in the manufacture of a dietary supplement.

*Reserve sample* means a representative sample of product that is held for a designated period of time.

*Sanitize* means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other 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 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 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 U.S. Food and Drug Administration (FDA).

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

### § 111.5 Do other statutory provisions and regulations apply?

In addition to this part, you must comply with other applicable statutory provisions and regulations under the act related to dietary supplements. For importers of dietary supplements and dietary supplement components, the regulation on foreign supplier verification programs can be found in subpart L of part 1 of this chapter.

[72 FR 34942, June 25, 2007, as amended at 80 FR 74352, Nov. 27, 2015]

## Subpart B—Personnel

### § 111.8 What are the requirements under this subpart B for written procedures?

You must establish and follow written procedures for fulfilling the requirements of this subpart.

## 21 CFR Ch. I (4–1–25 Edition)

### § 111.10 What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices?

(a) *Preventing microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material, including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. Such measures include the following:

(1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists; 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 result in microbial contamination of any components, dietary supplements, or any contact surface.

(b) *Hygienic practices.* If you work in an operation during which adulteration of the component, dietary supplement, or contact surface could occur, you must use hygienic practices to the extent necessary to protect against such contamination of components, dietary supplements, or contact surfaces. These hygienic practices include the following:

(1) Wearing outer garments in a manner that protects against the contamination of components, 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