

operations and to sanitizing operations. Although these terms appear to be similar, they are distinct in the sense that a sanitizing operation usually produces a sterile (free of living microorganisms) environment whereas a cleaning operation may not. To illustrate the difference, if you wipe a contact surface with a wet cloth to remove any components or dietary ingredients, you would have engaged in a cleaning operation. The contact surface is free of noticeable debris, but it might still contain microorganisms. In contrast, if you used a disinfectant on the contact surface in order to eliminate any possible microorganisms on that surface, you would have engaged in a sanitizing operation.

Size, construction, and design of a physical plant are important to manufacturing, packaging, and holding dietary ingredients and dietary supplements that are not adulterated because they can help you identify and eliminate possible sources of contamination that result in or may lead to adulteration. For example, condensation can occur on water pipes. If these pipes are exposed and run above a contact surface, condensation from those pipes may fall onto the contact surface and adulterate your dietary ingredients or dietary supplements. So, if you design your physical plant to eliminate exposed pipes or to shield your contact surfaces from condensation, you would eliminate a possible source of adulteration.

As another example, you might find it more practical to clean certain floors in your physical plant by spraying them with water. Obviously, a floor design that uses floor drains would facilitate the cleaning of those floors.

Proposed § 111.20(b) would require your physical plant to have adequate space for the orderly placement of equipment and holding of 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. Adequate space for the orderly placement of equipment and holding of materials is important because it can directly affect your ability to maintain, clean, or sanitize your equipment or physical plant effectively. For example, assume that your manufacturing operation involves the use of a large mixer. However, the mixer is installed in a small room which makes it difficult to open the mixer fully. This may make it difficult for you to maintain and clean the mixer properly and, as a result, may increase the possibility that residues in

the mixer will contaminate the next batch of ingredients that go into the mixer.

Proposed § 111.20(c) would require your physical plant to 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. The proposal would require the physical plant to have, and require that you 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 specific operations. The specific operations would be listed at proposed § 111.20(c)(1) through (c)(7) and are as follows:

- 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;
- 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;
- 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;
- Performing laboratory analyses and holding laboratory supplies and samples;
- Cleaning and sanitizing contact surfaces;
- Packaging and label operations; and
- Holding dietary ingredients or dietary supplements.

The proposal would not specify the types of precautions your physical plant must have to reduce the potential for mixups or contamination. The precautions may depend on your physical plant and the products you make. For example, depending on your physical plant's size and layout, you may be able to receive components and dietary ingredients at one location, hold them in another location and store rejected components and dietary ingredients in yet another location.

However, if your physical plant does not allow for physically separate areas, you would have to develop an alternative approach for segregating components, dietary ingredients, and dietary supplements at points when they are received, stored, and rejected.

Proposed § 111.20(d) would require that your physical plant be designed and constructed in a manner that prevents contamination of components, dietary ingredients, dietary supplements, or contact surfaces. The proposal would require that the design and construction include floors, walls, and ceilings that are of smooth and hard surfaces that may be adequately cleaned and kept clean and in good repair. Smooth, hard surfaces are necessary because they are easier to clean and sanitize than those surfaces that are not smooth and hard. The proposal also would require that you use fixtures, ducts, and pipes that do not contaminate components, dietary ingredients, dietary supplements, or contact surfaces by dripping or condensate. Condensation may contain microorganisms or contaminants that can contaminate your components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed § 111.20(d) also would require your physical plant's design and construction to:

- Use 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. Adequate ventilation or environmental control equipment is a necessary part of your physical plant's design and construction because some contaminants and microorganisms may be airborne, so a failure to provide adequate ventilation will increase your chances of airborne contamination. In addition, some potentially harmful gases (such as carbon monoxide and carbon dioxide) are colorless and odorless, so it is important to have a ventilation or environmental control system that minimizes odors and vapors;
- Use 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;
- Use equipment to control temperature and humidity. For example, high temperatures may stimulate