

where good hygienic practices require your employees to wash or sanitize (or to both wash and sanitize) their hands.

One comment to the ANPRM suggested that, instead of requiring employees to wash “and/or” sanitize their hands, we should require employees to wash “or” sanitize their hands.

We disagree with the comments. In some cases, it is necessary to both wash and sanitize the hands. Sanitizing which generally refers to the removal or elimination of living microorganisms, may be more effective if the hands are washed before they are sanitized, and washing, alone, will not sanitize the hands. Therefore, the proposed rule would address situations where good hygienic practices require employees to wash or sanitize their hands or to wash and sanitize their hands.

Proposed § 111.15(h)(2) and (h)(3) would require that you provide effective hand-cleaning and sanitizing preparations and air driers, sanitary towel service, or other suitable drying devices. Disposable paper towels would be an example of sanitary towel service.

One comment to the ANPRM suggested replacing “effective hand-cleaning and sanitizing preparation” with “commonly available” hand-washing and sanitizing preparations.

We disagree with the comment. The purpose behind proposed § 111.15(h)(2) is to ensure that hand-cleaning and sanitizing preparations are effective. While we have objection to the use of “commonly available” hand-washing and sanitizing preparations if they are “effective,” the effectiveness of the hand-washing and sanitizing preparation is essential to ensuring that the hand-washing and sanitizing preparation will prevent adulteration of the product.

Another comment to the ANPRM suggested that a dietary supplement CGMP rule mention paper towels as a hand drying device.

We have drafted proposed § 111.15(h)(3) to identify disposable paper towels as an example of sanitary towel service. However, under proposed § 111.15(h)(3), the paper towels must be both sanitary and disposable.

Another comment to the ANPRM suggested that paper towels used in hand-washing facilities should be made from recycled paper.

We take no position regarding the use of paper towels made from recycled paper. The proposal neither requires nor prohibits the use of paper towels made from recycled paper.

Proposed § 111.15(h)(4) would require that you provide devices or fixtures that are constructed to prevent

recontamination of clean, sanitized hands. For example, if sanitized hands are necessary at a particular location, you might install hand sanitizing facilities that can be activated by foot pedals or by motion so that your employees do not have to use their hands—and, by doing so, risk contaminating their hands—to turn on the hand sanitizing equipment.

Proposed § 111.15(h)(5) would require that you have easily-understood signs and to post them throughout your physical plant to direct your employees who handle components, dietary ingredients, dietary supplements, or contact surfaces to wash and, where appropriate, sanitize their hands:

- Before they start work,
- After each absence from their duty station, and
- When their hands may have become soiled or contaminated.

Proposed § 111.15(h)(6) would require that you have trash bins that are constructed and maintained in a manner to protect against recontamination of hands and contamination of components, dietary ingredients, dietary supplements, or any contact surface. The proposal would not specify any particular type of trash bin to use.

Proposed § 111.15(i) applies to trash disposal. The proposal would require that you convey, store, and dispose of trash to minimize the development of odors; to minimize the potential for trash to attract, harbor, or become a breeding place for pests; to protect against contamination of components, dietary ingredients, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant and to control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

Proposed § 111.15(j) would require that you assign one or more employees to supervise overall sanitation. Under the proposal, the employee or employees would have to be qualified by training and experience to develop and supervise sanitation procedures. The proposal would give you discretion in deciding how many employees you need to assign to supervise overall sanitation of your physical plant. As previously discussed, the proposed requirement does not preclude the possibility of a one-person operation. If you are a one-person operation, you would need to be qualified by training and experience to develop and perform all sanitation procedures.

We invite comment on whether written procedures for maintenance, cleaning, and sanitation should be required in a final rule. If comments

assert that written procedures are necessary, comments should include an explanation of why the requirement is necessary to prevent adulteration including how such a requirement would ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. Conversely, if comments assert that written procedures are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement.

We invite comment on whether documentation at the time of performance of equipment, utensil, and contact surface maintenance, cleaning, and sanitation and keeping such records should be required in a final rule. This would give you a record that you would be able to consult if any questions regarding maintenance, cleaning, and sanitation of equipment used in producing the batch arise. We seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

2. What Design and Construction Requirements Apply to Your Physical Plant? (Proposed § 111.20)

Proposed § 111.20 would describe the general requirements for physical plant construction and design that are necessary to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, and holding.

Proposed § 111.20(a) would require any physical plant you use in the manufacturing, packaging, or holding of dietary ingredients or dietary supplements to be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations. You should note that proposed § 111.20(a) refers to cleaning