

contact surface. Outer garments may include gowns or aprons;

- Maintaining adequate personal cleanliness;

- Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility:

1. Before starting work; and

2. At any time when hands may become soiled or contaminated. Hands may become soiled or contaminated after meals or after using the bathroom;

- Removing all unsecured jewelry and other objects that might fall into components, dietary ingredients, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods when you manipulate components, dietary ingredients, or dietary supplements by hand. If the hand jewelry cannot be removed, the proposal would require that it be covered by material that is intact, clean, and in sanitary condition that effectively protects against contamination of your components, dietary ingredients, or dietary supplements, or contact surfaces.

- Maintaining gloves used in handling components, dietary ingredients, or dietary supplements in an intact, clean, and sanitary condition;

- Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other hair restraints;

- Not storing clothing or other personal belongings in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed;

- Not eating food, chewing gum, drinking beverages, and using tobacco products in areas where components, dietary ingredients, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed; and

- Taking any other necessary precautions to protect against contamination of components, dietary ingredients, dietary supplements, or contact surfaces by microorganisms, filth, or other extraneous materials, including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

Each of these procedures is necessary because good personal hygiene should help prevent contamination from microbial sources (such as bacteria) as well as from nonmicrobial sources (such as dirt and hair).

We seek comment on whether we should require, in a final rule, that you

establish and follow written procedures to ensure that you comply with the requirements of that section. As stated previously, we invite comment on whether such written procedures should be required in a final rule, and whether there are other procedures, that we should include 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. Further, 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.

A comment to the ANPRM stated that any requirements on disease control should be limited to manufacturing, processing, and handling of raw agricultural material and are not appropriate for manufacturing dietary supplements derived from chemicals. The comment stated that chemical processes are carried out in closed pipes and vessels, so the risk for human contamination is very low. The comment, therefore, said that FDA should allow workers who have wounds to continue working in manufacturing operations.

We disagree that the regulations on disease control should be limited to manufacturing, processing, and handling raw agricultural material. Because contamination may occur at any time during manufacturing, packaging, or holding operations, requirements concerning disease control

must apply to all operations where a person may contaminate a component, dietary ingredient, dietary supplement, or contact surface. For example, an employee could contaminate a dietary supplement (of agricultural origin or synthetic origin) or contact surface during packaging operations. However, if we adopted the comment's suggested limitation, contamination of a synthetic dietary supplement could occur, and there would be no regulatory requirement to guard against such contamination.

As for employees with open wounds, proposed § 111.10(a) would require that you exclude a person with an open lesion or any other abnormal source of microbial contamination from any operation which may adulterate the component, dietary ingredient, dietary supplement, or contact surface. Whether the proposed rule would require that you exclude a person with an open lesion or another abnormal source of microbial contamination from working in a closed system area, such as when the product is contained completely in closed pipes or vessels, would depend on whether, as a result of exposure, there would be a reasonable possibility of the component, dietary ingredient, dietary supplement, or contact surface becoming contaminated. Thus, when a dietary ingredient or dietary supplement is manufactured in a completely closed system, this proposed requirement on open lesions might not apply if there is no reasonable possibility of contamination. However, you must take the measures that would be required by § 111.10(a) if there is a reasonable possibility that any person might cause contamination of components, dietary ingredient, dietary supplements, or contact surfaces.

Comments to the personnel provisions, and other provisions, stated that the industry-drafted outline used phrases such as "includes, but are not limited to," when giving examples of how to comply with various requirements. The comments suggested that this phrase be changed to "may include" to clarify that items that follow the phrase are simply examples of how to comply with a particular requirement and are not binding or do not represent an exhaustive list of examples.

We decline to draft the proposal as suggested by the comments because we do not agree that when we state "includes, but are not limited to," we are providing examples of how to comply with the regulations. When we state that a regulation requires a manufacturer, packager, or holder to establish certain practices which "includes, but is not limited to" a list