

used to make tablets) or gelatin (which is used to make capsules), might be used to produce dietary supplements; these ingredients remain in the finished product, but would be “components” under the proposed rule.

Proposed § 111.3 defines “consumer complaint” as:

* * * communication that contains any allegation, written or oral, expressing dissatisfaction with the quality of a dietary ingredient or a dietary supplement related to good manufacturing practices. Examples of product quality related to good manufacturing practices are: Foul odor, off taste, superpotent, subpotent, wrong ingredient, drug contaminant, other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead), disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a dietary supplement container, improper packaging, or mislabeling. For the purposes of this regulation, a consumer complaint about product quality may or may not include concerns about a possible hazard to health, which would include a consumer complaint. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices.

Communication about prices, package size or shape, or other matters that could not possibly reveal the existence of a hazard to health or do not concern the appearance, taste, odor, or quality of a dietary ingredient or a dietary supplement are not considered “consumer complaints” under the proposed rule. Consumer complaints related to an illness or injury related to a pharmacologically active substance of a dietary ingredient such as aristolochic acid would not be related to good manufacturing practices. The use of products containing aristolochic acid has resulted in several life-threatening adverse incidents. Aristolochic acids are potent carcinogens and nephrotoxins that are present, primarily, in plants of the family Aristolochiaceae. A product that contains a large amount of it may result in the rapid onset of acute toxicity symptoms in a consumer using the product. A product containing a small amount could be used for years with no apparent adverse effects, until serious, irreversible effects, such as renal failure, has occurred. Such adverse effects are related to a pharmacologically active substance of a particular dietary ingredient, aristolochic acid. Thus, for the purpose of this regulation, a communication from a consumer that contains any allegation, written or oral, related to the safety of the use of a product because it contained a particular dietary ingredient, e.g.,

aristolochic acid would not be considered a “consumer complaint.” We consider that a dietary supplement containing a dietary ingredient such as aristolochic acid, a substance that is nephrotoxic and carcinogenic, is adulterated under section 402(a)(1), (f)(1)(A), and (f)(1)(D) of the act.

Proposed § 111.3 defines “contact surface” as:

* * * any surface that contacts a component, dietary ingredient, or dietary supplement, and those surfaces from which drainage onto the component, dietary ingredient, or dietary supplement, or onto surfaces that contact the component, dietary ingredient, or dietary supplement ordinarily occurs during the normal course of operations.

Proposed § 111.3 gives some examples of contact surfaces, such as containers, utensils, tables, contact surfaces of equipment, and packaging. Under the proposed definition the term drainage includes both liquid and dry materials.

The proposed definition of “contact surface” is similar to the definition of “food-contact surface” in § 110.3(g), except we have used the terms “component, dietary ingredient, or dietary supplement” instead of food, and we have added several examples of contact surfaces. The proposed definition would include the inside of containers.

Proposed § 111.3 defines “ingredient” as “any substance that is used in the manufacture of a dietary ingredient or a dietary supplement that is intended to be present in the finished dietary ingredient or dietary supplement.” The proposed definition would explain that an ingredient “includes, but is not necessarily limited to, a dietary ingredient as described in section 201(ff) of the act.” Thus, under proposed § 111.3, an “ingredient” may be a substance that is present in the finished dietary ingredient or dietary supplement that is intended to have some activity (such as a vitamin, mineral, or amino acid), but could also be a substance that is not intended to have any activity (such as the gelatin used to make the capsule holding the dietary ingredients). This proposed definition and the proposed definition for “component” in proposed § 111.3 differ in that “component” includes the various materials used to manufacture a dietary supplement that may not appear in the final product. Because an ingredient is defined as a substance that is intended to be present in the finished dietary ingredient or dietary supplement and a component is defined as a substance that may or may not be included in the finished dietary ingredient or dietary supplement, all

ingredients are components but not all components are ingredients.

Proposed § 111.3 defines “in-process material” as “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.” In-process material differs from a component because in-process material is created and used during manufacturing. For example, assume you manufacture a dietary supplement in hard tablet form. During the manufacturing process, you mix various ingredients, and you add binding agents and water to mix the ingredients thoroughly before making individual tablets. The mixture would be an “in-process material” because it is a blend or processed material that you will use to make your dietary supplement.

Proposed § 111.3 defines “lot” to mean:

* * * a batch, or a specific identified portion of a batch intended to have uniform identity, purity, quality, strength, and composition; or, in the case of 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.

The proposed definition for “lot” is similar to the definition for “lot” in the proposed CGMP regulations for infant formula (61 FR 36154 at 36209, July 9, 1996), but would refer to “identity, purity, quality, strength, and composition” instead of “character and quality” to reflect the different characteristics of dietary ingredients and dietary supplements.

Proposed § 111.3 defines “microorganisms” as “yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern.” The proposed definition would include, but would not be limited to, species that:

- Have public health significance;
- Could cause a component, dietary ingredient, or dietary supplement to decompose;
- Indicate that the component, dietary ingredient, or dietary supplement is contaminated with filth; or
- Otherwise may cause the component, dietary ingredient, or dietary supplement to be adulterated.

The definition of “microorganisms” includes microorganisms of public health concern and microorganisms that are of sanitary concern. Proposed § 111.3 is similar to the definition of microorganism in § 110.3 but we added