

an herbalist practitioner introduces or delivers for introduction into interstate commerce, a dietary ingredient or dietary supplement, that practitioner must use the same good manufacturing practices as other manufacturers to ensure that their clients receive dietary supplements that are not adulterated. The risks of adulteration are not eliminated just because the practitioner is an herbalist. Therefore, we decline to exempt "herbalist" practitioners who manufacture dietary ingredients and dietary supplements. Herbalist practitioners who introduce or deliver for introduction into interstate commerce, a dietary ingredient or dietary supplement, are manufacturers who must meet CGMPs.

2. What Are These Regulations Intended To Accomplish? (Proposed § 111.2)

Proposed § 111.2, entitled "What are these regulations intended to accomplish?" discusses the purpose of the CGMP regulations. The proposal states that the regulations establish the minimum CGMPs that you must use to the extent that you manufacture, package, or hold a dietary ingredient or dietary supplement. By using the phrase "to the extent," we mean that you must comply with the provisions that are applicable to you or to the operations that you perform and that, depending on the type of operations you perform, some provisions may not apply to you. For example, some provisions discuss requirements for automatic, mechanical, and electronic equipment; if you do not use such equipment, you would not have to comply with those provisions.

Our primary purpose in proposing these regulations is to protect consumers from adulterated and misbranded dietary supplements due to improper manufacturing, packaging, or holding practices. By observing CGMP regulations that require that dietary ingredients and dietary supplements are manufactured, packaged, or held in a controlled environment, manufacturers can ensure that dietary ingredients and dietary supplements are not adulterated or misbranded during manufacturing, packaging, and holding operations. Manufacturing, packaging, and holding dietary ingredients and dietary supplements under CGMPs will provide consumers with greater confidence that dietary supplements contain the dietary ingredients that they are supposed to contain and that these dietary ingredients were evaluated for their identity, purity, quality, strength, or composition. The CGMP regulations, if finalized as proposed, would require a manufacturer to establish specifications for the dietary ingredients and dietary

supplements that it makes. Thus, under the proposed CGMPs, a dietary supplement with a particular dietary ingredient listed on its label must contain that particular dietary ingredient. Moreover, that dietary ingredient must meet certain specifications that the manufacturer establishes as to the purity, quality, strength, and composition. CGMPs are intended to ensure that a dietary supplement contains what the label says it contains. If it does not, the dietary supplement would not only be misbranded under section 403 of the act, but also would be adulterated under section 402(g) of the act.

3. What Definitions Apply to This Part? (Proposed § 111.3)

Proposed § 111.3 defines various terms used in proposed part 111. In general, we have used definitions that are similar to definitions in part 110 for food and other CGMP regulations. However, we have modified some definitions for "plain language" purposes under the presidential "plain language" memorandum (Ref. 43) and to make other definitions more appropriate for dietary ingredients and dietary supplements.

In some cases, we based a definition on provisions in the industry outline published in the ANPRM. However, we did not adopt all of the definitions in the industry outline. For example, the industry outline defined terms such as, "adequate," "composition," "raw material," "representable sample," and "rework." We omitted those definitions from this proposal because the terms are generally understood, or because definitions for those terms are unnecessary for purposes of understanding the proposed rule.

Proposed § 111.3 states that the definitions and interpretations of terms in section 201 of the act apply to such terms when used in these regulations. Section 201 of the act defines various terms that appear throughout the act, including "dietary supplement" (*see* section 201(ff) of the act). Other terms in section 201 of the act, such as "label" (section 201(k) of the act) and "pesticide chemical" (section 201(q)(1) of the act), have a long history of use. The definitions and interpretations of such terms apply when we use those terms in this rule.

Proposed § 111.3 defines specific terms used in the proposal.

Proposed § 111.3 defines "batch" as "a specific quantity of a dietary ingredient or dietary supplement that is intended to meet specifications for identity, purity, quality, strength, and composition, and is produced during a

specified time period according to a single manufacturing record during the same cycle of manufacture."

The phrase "identity, purity, quality, strength, and composition," means that the production on a batch-by-batch basis is consistent with the master manufacturing record and is what it is represented on the label to be (identity); is without impurities and is the desired product (purity); is the identity, purity, and strength for its intended purpose (quality); is the concentration, that is, the amount per unit of use intended (strength); and is the intended mix of product and product-related substances (composition).

Proposed § 111.3 defines "batch number, lot number, or control number" as "any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, or holding of a batch or lot of dietary ingredients or dietary supplements can be determined." You should note that the proposed definition would have the batch, lot, or control number be "distinctive," which means, for the purposes of this proposal, that it is unique in some fashion, and is not a reused number. Numbers must be distinctive because, if a problem involving a marketed dietary ingredient or dietary supplement later results, a distinctive batch number will make it possible for you to investigate the source of the problem and the manufacturing history for the batch. This would help you to take appropriate actions concerning that batch more quickly.

Proposed § 111.3 defines "component" as "any substance intended for use in the manufacture of a dietary ingredient or dietary supplement including those that may not appear in the finished dietary ingredient or dietary supplement." Proposed § 111.3 states that "component" includes ingredients and dietary ingredients as described in section 201(ff) of the act. Under proposed § 111.3, components would include ingredients, dietary ingredients, manufacturing aids (such as solvents that are removed during manufacturing), and reagents that are used to synthesize a product.

Under the proposed definition of "component," a component may or may not appear in the finished product. For example, solvents that are used to produce herbal extracts do not necessarily appear in a finished dietary supplement, but the proposed rule still would consider the solvents to be "components." As another example, ingredients, such as cellulose (which is