

#### *F. Proposal Highlights and Requests for Comments*

This proposed rule is intended to ensure that manufacturing practices will not result in an adulterated dietary supplement and that supplements are properly labeled. This proposed rule, if finalized as proposed, will give consumers greater confidence that the dietary supplements they choose to use will have the identity, strength, purity, quality, or composition claimed on the label. A manufacturer of a dietary ingredient or a dietary supplement cannot make claims that state or imply that the dietary ingredient or dietary supplement is safe and/or effective simply because it has been manufactured in compliance with current good manufacturing practice (CGMP) requirements. However, we believe that a voluntary labeling statement about the fact that a dietary ingredient or dietary supplement has been made in compliance with CGMP requirements might be made lawfully under the act, provided that such a statement is made in an appropriate context and with adequate disclaimers so that consumers fully understand it and are not misled by it. The proposed rule governing CGMP requirements for dietary supplements address manufacturing controls to ensure that dietary ingredients and dietary supplements are produced in a manner that will not adulterate or misbrand such products. Compliance with any final rule, based on the proposal, will not ensure that the dietary ingredient or dietary supplement itself is safe or effective. Thus, the agency believes that an unqualified statement saying simply "produced in compliance with dietary supplement current good manufacturing practice requirements," without more, could well suggest that a product may be safe and effective or somehow superior to other dietary ingredient and dietary supplement products that are subject to the same CGMP requirements. Such a statement would likely be considered misleading by FDA under sections 403(a)(1) and 201(n) of the act. We believe however, that it might be possible to cure an unqualified statement by including language clarifying to consumers that all dietary ingredients and dietary supplements must be manufactured in compliance with CGMP requirements and that such compliance does not mean that the dietary ingredient or dietary supplement is safe or effective. As usual, the manufacturer would be responsible for ensuring that any such voluntary labeling statements on its dietary ingredient and dietary supplement

products are truthful and not misleading. The agency would review the lawfulness of such statements under sections 403(a)(1) and 201(n) of the act.

We propose requirements for: (1) Personnel, (2) the physical plant environment, (3) equipment and utensils, (4) production and process controls, (5) holding and distributing, (6) consumer complaints related to CGMPs, and (7) records and recordkeeping. Key provisions of the proposed rule are highlighted below.

We also seek comment on whether certain additional provisions should be included as requirements in a final rule.

Proposed "personnel" requirements would require that you have qualified employees and supervisors, to take measures to exclude any person from your operations who might be a source of microbial contamination, and to use hygienic practices to the extent necessary to protect against contamination.

Proposed "physical plant" requirements are intended to help prevent contamination from your physical plant environment. You would be required to design and construct your physical plant in a manner to protect dietary ingredients and dietary supplements from becoming adulterated during manufacturing, packaging, and holding. You would be required to keep your physical plant in a clean and sanitary condition and in sufficient repair to prevent contamination of components, dietary ingredients, dietary supplements, or contact surfaces.

Proposed "equipment and utensils" provisions would require that you use equipment and utensils that are of appropriate design, construction, and workmanship for their intended use and that you provide for adequate cleaning and maintenance. You would be required to maintain and calibrate your instruments and controls for accuracy and precision and to ensure that automatic, mechanical, and electronic equipment works as intended. You would also be required to maintain, clean, and sanitize, as necessary, all equipment utensils and contact surfaces that are used to manufacture, package, or hold dietary ingredients or dietary supplements.

Under the proposed "production and process controls" requirements, you would be required to establish and use a quality control unit in your manufacturing, packaging, and label operations. We propose requirements for establishing and using master manufacturing records and batch control records to ensure batch-to-batch consistency. Specifications would be required for any point, step, or stage in

the manufacturing process where control is necessary to ensure that the dietary supplement contains the identity, purity, quality, strength, and composition claimed on the label. We propose flexible testing requirements: You would be required to test final products for adherence to specifications, unless a scientifically valid analytical method does not exist; in the latter case, you would be required to test incoming shipment lots of components, dietary ingredients, or dietary supplements for any such specification, and to test in-process for any such specification in accordance with the master manufacturing record where you determine control is necessary to ensure the identity, purity, quality, strength, and composition of the product.

Proposed "holding and distributing" requirements would protect components, dietary ingredients, dietary supplements, packaging, and labels against contamination and deterioration. You would be required to hold components, dietary ingredients, dietary supplements, packaging, and labels under appropriate conditions of temperature, humidity, and light so that their quality is not affected; and under conditions that do not lead to the mixup, contamination, or deterioration.

Proposed "consumer complaints" requirements would require that you keep a written record of each consumer complaint related to good manufacturing practices; review such complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those that may result in a possible risk of illness or injury (*i.e.*, an adverse event); and investigate a consumer complaint when there is a reasonable possibility of a relationship between the consumption of a dietary supplement and an adverse event. For the purposes of this regulation, a consumer complaint about product quality may or may not include concerns about a possible hazard to health. 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.

Proposed "records and recordkeeping" requirements would tell you how long you must keep certain records to show how you complied with the CGMP requirements. We would require that you keep written records for 3 years beyond the date of manufacture of the last batch of dietary ingredients