

or spread of communicable diseases between States. Thus, the agency is invoking its authority under the PHS Act in this proposed rule to prevent the spread of communicable disease from dietary ingredients or dietary supplements in intrastate and interstate commerce.

In developing proposed CGMPs for dietary supplements, we relied on the basic concept underlying the food CGMPs and upheld by the courts. As a result, the basic concept for the food CGMPs and the proposed dietary supplement CGMPs is the same: To establish regulations that will help ensure that your practices for preparing, packaging, and holding dietary ingredients and dietary supplements do not result in an adulterated food entering interstate commerce.

In addition to relying on the broad authority in relevant sections of the act that we used to issue the food CGMP regulations, we look to the other relevant statutory language in section 402(g) of the act and the act as a whole in deciding the basis for our legal authority in proposing regulations related to the manufacture, packaging, and holding of dietary ingredients and dietary supplements. We note that certain terms Congress used in section 402(g)(2) of the act, *i.e.*, “standards” and “current and generally available analytical methodology,” show that Congress intended to give us the authority to establish regulations in this rule that do not have parallel provisions in other food CGMPs. Specifically, the second phrase of the second sentence in section 402(g)(2) of the act states that we “may not impose standards for which there is no current and generally available analytical methodology.” “Standards” and “current and generally available analytical methodology” are terms of art in the scientific field, and we are relying on the meaning of these terms in the field of science in these proposed CGMPs regulations, which implement that provision. This statutory language does not limit CGMPs for dietary supplements solely to the food CGMP regulations at the time DSHEA was enacted. If Congress had intended for the CGMPs for dietary supplements to be identical to the CGMPs for food, the language in section 402(g)(2) of the act relating to “standards” and “current and generally available analytical methodologies]” would be meaningless. Thus, CGMP regulations for dietary ingredients and dietary supplements may include provisions relevant to dietary ingredients and dietary supplements that were not in current food regulations at the time DSHEA was enacted.

In addition to the broad authority in section 402(g) of the act, we look to the statutory scheme of DSHEA as a whole in proposing regulations related to the manufacture, packaging and holding of dietary ingredients and dietary supplements. Section 403(q)(5)(F) of the act (section 7(b) of DSHEA) requires that a dietary supplement product provide nutrition information. To comply with section 403(q)(5)(F) of the act, you must be able to identify the dietary ingredient or ingredients in a dietary supplement and the quantity of each. Moreover, the provisions in section 403(s) of the act relate to identity, purity, quality, strength, and compositional specifications of a dietary supplement. Thus, Congress sought to ensure in DSHEA that dietary supplements would provide accurate information to the consumer on the identity of the dietary ingredient and, if an herb or botanical, the source from which it is derived. Moreover, Congress sought to ensure that the dietary supplement would have the strength or meet the quality, purity, and compositional specifications that the dietary supplement is represented to meet. Because Congress established section 403(s) of the act—a provision that requires that a dietary supplement that bears representations about identity, purity, quality, strength, and compositional specifications meet those representations—it is reasonable for us to establish regulations for manufacturing, packaging, and holding addressing those same features. These representations relate to characteristics and hazards to which dietary supplements are subject. Further, in section 402(f) of the act, Congress identified circumstances under which a dietary supplement or a dietary ingredient would be deemed adulterated because it may present a significant or unreasonable risk of illness or injury. Congress expected that a dietary supplement would be manufactured in a way that ensures that the dietary supplement contains dietary ingredients that do not present an unreasonable risk of illness or injury and for which the conditions of use are based. Because one must be able to measure or analyze a dietary ingredient in order to determine whether a supplement in fact contains that dietary ingredient, it is reasonable for a proposed rule on CGMPs to include provisions related to identity, purity, quality, strength, and composition of a dietary ingredient or a dietary supplement. Moreover, it is reasonable to propose a requirement that records of complaints be kept and investigations be done, as necessary, so that the manufacturer and FDA can be

aware of any potential problems relating to a particular dietary ingredient and these CGMPs, and so that a manufacturer can take appropriate action when necessary. The proposed CGMPs would reflect the act’s regulatory scheme generally and, more specifically, DSHEA’s provisions that contemplate consistent, controlled manufacture of dietary supplements (*see* sections 402(f) and 403(q)(5)(F) and (s) of the act). We tentatively conclude that, therefore, section 402(g)(2) of the act gives us the authority to develop dietary supplement CGMPs that are not identical to our food CGMPs and that are appropriately tailored to the manufacturing, packaging, and holding of dietary ingredients and dietary supplements.

Sections 701(a) and 704 of the act also give us authority to establish regulations related to CGMPs for dietary ingredients and dietary supplements. Under section 701(a) of the act, we have the authority to issue regulations for the efficient enforcement of the act, and such regulations have been held to have the force and effect of law (*see National Nutritional Foods Ass’n v. Weinberger*, 512 F.2d 688, 697–98 (2d Cir. 1975)). Section 704 of the act gives us the authority to inspect factories, warehouses, and other establishments in which foods, including dietary ingredients and dietary supplements, are manufactured, processed, packed, or held and to inspect their facilities, equipment, finished and unfinished materials, containers, and labeling.

In addition to having the authority to establish broad regulations for manufacturing, packaging, and holding dietary ingredients and dietary supplements, we also have the authority to require recordkeeping as part of these regulations. Two questions that we considered in deciding whether to propose requirements for recordkeeping included whether the statutory scheme as a whole justified the proposed regulation and whether the proposed recordkeeping requirements would be limited, would clearly assist in the efficient enforcement of the act, and would not create an unreasonable recordkeeping burden. In the other relevant sections of this document, we explain in more detail the recordkeeping provisions that we believe are limited to what are necessary for the efficient enforcement of the act, and because the requests are limited, would therefore not create an unreasonable recordkeeping burden.

For this proposed CGMP rule for dietary ingredients and dietary supplements, recordkeeping is necessary to provide the type of