

or dietary supplements associated with those records and have all required records, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when requested.

CGMP records document the manufacturer's operation throughout time and are essential to an enforceable regulation. Because FDA does not observe the manufacturer's operation fulltime, records can ensure that the FDA has the information needed to identify noncompliance and to bring a non-compliant manufacturer into compliance. Records can show that appropriate monitoring is performed, pinpoint with confidence when a deviation began and ended, and prove that required quality control measures and practices were performed as often as necessary to ensure control. Review of manufacturing records with sufficient frequency can ensure that any problems are uncovered promptly and can facilitate prompt modification, have an impact on the production of subsequent batches of the product, and prevent introduction of potentially hazardous dietary supplements into the market place. Review of consumer complaint records can facilitate the identification of trends in reports of illness or injury, identify related batch records to identify previously undetected manufacturing deviation, and have an impact on the prompt recall of any potentially hazardous dietary supplement.

We seek comment on whether the proposed recordkeeping requirements are not necessary to prevent adulteration; to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement; to an enforceable regulation; and for the other reasons cited. If comments assert that recordkeeping provisions are not necessary, comments should include an explanation of why recordkeeping requirements are not necessary including how, in the absence of the requirements, one can prevent adulteration, ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement, ensure an enforceable regulation, and the other reasons cited. If comments agree that the recordkeeping requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

Although records are not required in 21 CFR Part 110, CGMPs in manufacturing, packing, or holding human food, records are required in the other commodity-driven food CGMPs (*i.e.*, 21 CFR Part 129, Processing and

bottling of bottled drinking water; 21 Part CFR 120, Hazard Analysis and Critical Control Point (HAACP) Procedures for the Safe and Sanitary Processing and Importing of Juice; 21 CFR Part 123, Fish and fishery products; 21 CFR Part 106 Infant formula quality control procedures; and 21 CFR Part 113, Thermally processed low-acid foods packaged in hermetically sealed containers). Further, records are included in the CGMPs submitted to FDA by industry, the National Nutritional Foods Association Standards, the NSF International draft standards (Ref. 83), and the USP draft Manufacturing Practices for Dietary Supplements.

We seek comment on whether certain additional provisions should be included as requirements in a final rule. For example, we invite comment on whether a final rule should include a requirement for certain personnel records; for written procedures in a number of areas; for equipment verification; and for expiration dating and related testing. Written procedures are included in the dietary supplement CGMP outline submitted to FDA by industry, National Nutritional Foods Association standards, the NSF International draft standards, and the USP draft Manufacturing Practices. In order to limit the burden to manufacturers, FDA is not proposing to require written procedures. However, FDA is proposing that manufacturers maintain appropriate records to ensure the identity, purity, quality, strength, and composition of a given product and records that are necessary for efficient enforcement and to permit trace back. Although we have not proposed requirements for written procedures as did these other groups, we seek comment on whether such practices should be included in a final rule. Later in this document, we request comments on specific written procedures and describe FDA's current thinking concerning what could be included in such a written procedure.

We also seek comment on whether this rule should include specific requirements for the use of animal-derived dietary ingredients, and requirements for persons who handle raw agricultural commodities. Specific requests for comment of this type are contained below in relevant sections of this preamble.

II. General Issues

A. Legal Authority

We are proposing these regulations under sections 201, 393, 409, 701(a), 704, and 801 of the act (21 U.S.C. 321,

903, 348, 371(a), 374, and 381) and sections 402 and 403 of the act and section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264).

Section 402(g) of the act gives us explicit authority to issue a rule regulating conditions for manufacturing, packaging, and holding dietary supplements. Section 402(g)(1) of the act states that a dietary supplement is adulterated if "it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations." Section 402(g)(2) of the act authorizes us to, by regulation, "prescribe good manufacturing practices for dietary supplements." In addition, section 402(g)(2) of the act states that any such regulations "shall be modeled after current good manufacturing practice regulations for food and may not impose standards for which there is no current and generally available analytical methodology."

In section 402(g)(2) of the act, which describes the general parameters of CGMPs for dietary supplements, Congress stated that the regulations were to be "modeled after current good manufacturing practice regulations for food." To determine what Congress meant, we look to the plain meaning of the phrase. *Webster's II New Riverside University Dictionary* defines "model" as "[a] preliminary pattern serving as the plan from which an item not yet constructed will be produced" (Ref. 81). Thus, when Congress used the term "modeled after" Congress intended that we use the food CGMPs as a "preliminary pattern" for the dietary supplement CGMPs. If Congress had intended for the agency to adopt food CGMPs as the CGMPs for dietary supplements, Congress could have explicitly stated that dietary supplements were subject to food CGMPs.

The provisions in the dietary supplement CGMP proposal are modeled after food CGMPs. The general CGMP provisions for food in part 110 relate not only to insanitary production practices, but other practices, such as having appropriate quality control operations, to ensure that a food is manufactured in a manner that will not adulterate the food. Further, the CGMPs in part 110 describe the minimally acceptable practices for all food handling operations. They are not intended to cover specific issues that may relate to a particular product type, rather, are general provisions concerned with practices relating to the receiving, inspecting, quality control operations, packaging, segregating, processing, storing, and transporting of food. The specific provisions of the food CGMPs