

relying on a supplier's certification on § 110.80(a)(2) through (a)(4); these provisions allow food manufacturers to rely on a supplier's guarantee or certification that raw materials or other ingredients do not contain levels of microorganisms or toxins that may produce illness or are otherwise contaminated. The comments suggested various means for determining the reliability of a supplier's certification, including independent analysis, in-house testing, and review of protocols.

Other comments stated that, because the CGMP regulations in part 110 permit reliance on a supplier's certification and because section 402(g)(2) of the act specifies that the CGMP regulations for dietary supplements should be modeled after the CGMP regulations for food, a supplier's certification for dietary supplements must be acceptable.

We have considered the comments on whether a supplier's certification could provide adequate assurance that a dietary ingredient is what it purports to be and is not adulterated. We disagree that manufacturers may rely on such certifications to determine that an ingredient is not contaminated, for example, with filth or microorganisms. Using a supplier certification, guarantee, or certification in lieu of performing testing on each shipment lot of components, dietary ingredients, or dietary supplements is not appropriate because a supplier's certification or guarantee would not necessarily ensure that the identity, purity, quality, strength, or composition of a component, dietary ingredient or dietary supplement is met. We discuss testing requirements and why we believe that the use of supplier's guarantee or certification is not sufficient in lieu of a manufacturer's own testing in more detail later in this document.

Question 4. We asked for comments on whether a CGMP rule should require manufacturers to establish procedures to document, on a continuing or daily basis, that they followed preestablished procedures for making dietary supplements.

The ANPRM noted that the food CGMP regulations under part 110 do not require manufacturers to document that they are following established procedures prescribed for manufacturing a food. However, the ANPRM also noted that section 402(g) of the act does not preclude us from adopting CGMP requirements for dietary ingredients and dietary supplements that have no counterpart in part 110 if we have an appropriate basis for doing so.

Most comments generally supported requiring manufacturers to develop and

follow written procedures and noted that the industry outline in the ANPRM would require written procedures for many processes and functions. Some comments noted that written procedures and day-to-day records documenting that the procedures were followed will ensure that products are safely and properly manufactured on a day-to-day basis and that this can be confirmed by periodic independent internal audits. One comment stated that the manufacturer should be responsible for ensuring, through employee training, self-audit programs, and batch records, that quality control and other procedures prescribed for the manufacture of a dietary supplement are properly and diligently executed. Other comments stated that it is good business practice to ensure product quality through periodic review of records and quality control audits and that failure to establish procedures will result in product recalls, potential injury, and litigation for damages for defective goods.

Some comments objected to any requirement for written procedures or documentation that the procedures were followed. The comments stated that section 402(g)(2) of the act states that dietary supplement CGMPs must be modeled after the food CGMP regulations and the food CGMP regulations do not require written procedures or documentation that procedures were followed.

We agree with those comments that support the development and use of written procedures by manufacturers and are considering whether we should require written procedures in a final rule. We are proposing requirements for documenting certain operations and processes while not requiring written procedures to remove underlying costs for establishing and updating such written procedures while preserving the records necessary to permit trace back. When manufacturers develop and follow written procedures such procedures help to ensure that manufacturers produce a consistent dietary ingredient or dietary supplement that is of a predictable quality and that is not adulterated. Following written procedures and documenting compliance with those procedures will ensure regular performance of a firm's established programs and procedures and will provide additional assurance of effective communication of appropriate information from the firm management to the line personnel. We invite comment on whether written procedures should be required in a final rule, and whether there are other procedures, that we should include in a

final rule. We discuss written procedures for various stages of manufacturing, packaging, labeling, holding, and for handling consumer complaints later in this document.

We disagree, however, that records are not necessary to show that certain operations and processes are being performed. Records document that quality control operations and processes such as calibrating instruments and controls; manufacturing a dietary ingredient or dietary supplement batch; and handling consumer complaints were performed. We further discuss the basis for the proposed recordkeeping requirement for certain operations and processes later in this document. We believe that section 402(g) of the act allows us to require written procedures and documentation that the procedures were followed. As explained previously, such records may be necessary for ensuring that dietary ingredients and dietary supplements are manufactured, packaged, and held consistent with these regulations. Moreover, we believe that the fact that the food CGMPs in part 110 do not have recordkeeping requirements does not preclude us from proposing recordkeeping requirements in this proposed rule, although we seek further comment on the issue.

Question 5. We invited comment on whether dietary supplement CGMP regulations should require that firms have competent medical authorities evaluate reports of injuries or illnesses and to determine if followup action is necessary to protect the public health.

The ANPRM explained that many dietary supplements contain pharmacologically active substances, which distinguish dietary supplements from many foods, and some dietary supplements may contain potential allergens. Because the characteristics may result in adverse events in certain consumers, we asked whether we should consider requiring firms to take certain actions with respect to reviewing AERs. We also sought comments on whether a CGMP rule should require firms to establish procedures for determining whether a reported injury constitutes a serious problem, and what actions are to be taken when serious problems are identified.

Comments generally opposed requiring manufacturers to establish a procedure for evaluation and followup of reports of illness and injuries. Comments also opposed requiring that a competent medical authority evaluate all reports of illness or injuries to determine if followup action is necessary to protect the public health. Some comments, opposing requiring written procedures and evaluation,