

problems are associated with maintenance, cleaning, or sanitizing operations. Batch and lot information, as we stated earlier, will let you identify batches or lots that may have been affected by any equipment or utensil that was improperly maintained, cleaned, or sanitized.

Proposed § 111.50(d) and (e) would set forth your quality control unit's responsibilities regarding batch production records. These responsibilities relate to not only the review but the documentation of their review and decisions about whether a batch could be reprocessed. As we noted in our discussion of proposed § 111.37, the quality control unit has special knowledge and expertise to determine if a batch is produced correctly, that those records are complete, and that it is appropriate to reprocess a batch. The quality control unit also serves as a quality control check that the batch production record accurately follows the master manufacturing record. A quality control unit review of batch production records could have detected and corrected the previously discussed manufacturing error caused by use of the dietary ingredient with the incorrect selenium. Therefore, the review and documentation by the quality control unit of batch production records provides the necessary quality assurance to prevent the production of an adulterated dietary ingredient or dietary supplement.

Specifically, proposed § 111.50(d) would require your quality control unit to review in accordance with § 111.37(b)(5) the batch production record. If a batch production record deviates from the master manufacturing record, including any deviation from specifications, proposed § 111.50(d)(1) would require your quality control unit to conduct a material review and make a disposition decision and record any decision in the batch production record. Proposed § 111.50(d)(2) would instruct your quality control unit to not approve and release for distribution any batch of dietary ingredient or dietary supplement that does not meet all specifications.

Proposed § 111.50(e) would require your quality control unit to document in accordance with § 111.37(c) the review performed in accordance with proposed § 111.50(d). The proposal would require the quality control unit to document this review at the time it does the review and would require the review and documentation to include, but would not limit them to, the following:

- Review of component, dietary ingredient, and dietary supplement

receiving records including review of testing and examination results;

- Identification of any deviation from the master manufacturing record that may have caused a batch or any of its components to fail to meet specifications identified in the master manufacturing record;
- Records of investigations, conclusions, and corrective actions performed in accordance with proposed § 111.50(d); and
- The identity of the person qualified by training and experience who performed the investigation in accordance with proposed § 111.50(d).

Proposed § 111.50(f) would prohibit you from reprocessing a batch that deviates from the master manufacturing record unless your quality control unit approves it for reprocessing. Proposed § 111.50(f) also would prohibit you from reprocessing a dietary ingredient or dietary supplement if it is rejected because of contamination with microorganisms of public health significance or other contaminants, such as heavy metals because you cannot rely on reprocessing to correct public health concerns that a product with pathogens and/or heavy metals would present.

Proposed § 111.50(g) would require that you meet all specifications established in the master manufacturing record for any batch of dietary ingredient or dietary supplement that is reprocessed and would require your quality control unit to evaluate and approve the batch before releasing for distribution. This requirement is intended to ensure that a reprocessed batch is not subject to any lesser specifications than are otherwise applicable to a nonreprocessed batch. Proposed § 111.50(g) also would require that you document the results of the quality control unit's reevaluation in the batch production record.

Proposed § 111.50(h) would require that you collect representative reserve samples of each batch of dietary ingredient or dietary supplement and to keep the reserve samples for 3 years from the date of manufacture for use in appropriate investigations including, but not limited to, consumer complaint investigations to determine whether, for example, the dietary ingredient or dietary supplement associated with a consumer complaint failed to meet any of its specifications for identity, purity, quality, strength, and composition. Reserve samples also may prove helpful in investigating possible tampering or counterfeiting of your products. We invite comment on whether we should require, in a final rule, that you identify each reserve sample with the batch number so that you can readily identify

the correct reserve sample in the event that there is a problem with a particular batch.

Proposed § 111.50(i) would require that you keep your batch production records in accordance with proposed § 111.125. The batch production records in addition to the master manufacturing records will ensure that a complete history of each batch of dietary ingredient or dietary supplement is available for your review in the event that a problem arises with a particular batch. These records also are necessary to demonstrate compliance with the CGMP and quality control procedures.

6. What Requirements Apply to Laboratory Operations? (Proposed § 111.60)

Proposed § 111.60 would establish various requirements for laboratory operations. Proposed § 111.60(a) would require that you use adequate laboratory facilities to perform any necessary tests or examinations to determine that components, dietary ingredients, and dietary supplements you receive meet specifications; that specifications are met during inprocess as specified in the master manufacturing record; and that the dietary ingredients and dietary supplements you manufacture meet their specifications.

One comment to the ANPRM recommended that the regulations related to laboratory operations apply to laboratory facilities located and operated within a company and those facilities that a company may contract with that are located elsewhere. Proposed § 111.60(a) would apply to laboratory facilities generally and is not restricted to laboratory facilities located and operated within a company. In other words, even if you hire a private laboratory to perform various tests for you, proposed § 111.60(a) would require that you make sure that the private laboratory's facilities are adequate to perform whatever tests are necessary. The most important point in proposed § 111.60(a), however, is not where the facility is located, but whether the laboratory facility is adequate for the tests and examinations that need to be done.

Proposed § 111.60(b)(1) would require that you establish and follow laboratory control processes that the quality control unit has approved. For example, under proposed § 111.60(b)(1)(i) and (b)(1)(ii), the laboratory control processes would include use of criteria for selecting appropriate testing and examination methods and for establishing appropriate specifications. Specifications play an important role in CGMP's because they may help