

requirements in proposed part 111. The contractor, however, is also considered a manufacturer and must comply with the regulations that apply to the responsibilities that it has specifically contracted to perform.

Proposed § 111.50(c) would specify the batch production record's contents. The proposal would require that certain information be included in the batch production record including, but not be limited to, the following information:

- The batch, lot, or control number;
- Documentation, at the time of performance, showing the date on which each step of the master manufacturing record was performed, and the initials of the persons performing each step including, but not limited to, the person responsible for weighing or measuring each component used in the batch and the person responsible for adding the components to the batch;
- The identity of equipment and processing lines used in producing the batch;
- The date and time of the maintenance, cleaning, and sanitizing of the equipment and processing lines used in producing the batch;
- The shipment lot unique identifier of each component, dietary ingredient, dietary supplement, packaging, and label used;
- The identity and weight or measure of each component used;
- The initials at the time of performance or at the completion of the batch of the person responsible for verifying the weight or measure of each component used in the batch;
- The initials at the time of performance or at the completion of the batch of the person responsible for verifying the addition of components to the batch;
- A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;
- The actual test results for any testing performed during the batch production in accordance with § 111.35(m);
- Documentation that the dietary ingredient and dietary supplement meets specifications;
- Copies of all container labels used and the results of examinations conducted during the label operation to ensure that the containers have the correct label;
- Any documented material review and disposition decision in accordance with § 111.35(j); and
- The signature of the quality control unit to document batch production

record review and any approval for reprocessing or repackaging.

Proposed § 111.50(b) and (c) are necessary to ensure that you made your batches correctly under the master manufacturing record and that you correctly performed each significant step in the manufacturing process. If you did not create a batch production record for each batch production that accurately followed the master manufacturing record, you would not be sure that your dietary ingredient or dietary supplement was not adulterated. The master manufacturing record is intended to ensure batch to batch uniformity and to prevent adulteration. Your batch production record also may be valuable in the event of a product recall. We seek comment on whether any of the proposed requirements in this section are not necessary to prevent adulteration and to ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments assert that certain provisions are not necessary, comments should include an explanation of why the requirement is not necessary including how, in the absence of the requirement, one can prevent adulteration and ensure the identity, purity, quality, strength, and composition of the dietary ingredient or dietary supplement. If comments agree that the proposed requirements are necessary for reasons other than those we have provided, the comments should so state and provide an explanation.

In one case (Ref. 27), we found that a manufacturer had produced a subpotent folic acid product. When the manufacturer reviewed the batch production records, it discovered that the bulk product was not mixed properly, and this caused the folic acid to be distributed poorly throughout the product. Thus, in this instance, the batch production record helped identify the point in the manufacturing process when the error occurred, and the reason why the error occurred and enabled the manufacturer to correct the problem.

Review of batch production records might have prevented another incident where several persons experienced dizziness, vomiting, or lightheadedness after consuming vitamin and mineral products. As we mentioned in our discussion of proposed § 111.45, this incident involved a mixup during the manufacturing process where the manufacturer's master manufacturing record called for the use of a product having 0.2 percent selenium by weight, but the manufacturer's batch records showed that it used a product that had 5 percent selenium by weight. This difference meant that the supplements,

instead of containing 200 µg of selenium, contained between 400 to 4,699 µg of selenium. As discussed earlier, the quality control unit review and approval of the master manufacturing record would have noted the change in percent selenium by weight and the necessary changes to the master manufacturing record could have been made. The quality control unit review and approval of the batch production record provides another check to ensure that a mixup has not occurred. Had the manufacturer's quality control unit compared the master manufacturing record to the batch production record, it would have noticed the mixup during the manufacturing process and prevented the use of the higher percentage selenium dietary ingredient. The information that would be required under proposed § 111.50(c) would help you determine what product was manufactured, when it was manufactured, how it was manufactured, and where it was manufactured. As another example, if your batch production records identify the equipment and processing lines being used, you would be able to go to that piece of equipment or to that processing line and determine which dietary ingredient or dietary supplement is being manufactured or processed. Further, if your batch records reflect the initials of those persons who weighed a component, added that specific component, and performed a particular step to prevent adulteration of the product, you would be able to see who was responsible for a particular action and, if necessary, to consult that person in the event of a problem or to see how he or she performed a particular task. In addition, if your batch production records contain batch or lot numbers and if you later discover a problem with a particular batch, that information will help you investigate the problem by showing you the manufacturing history for that particular batch.

A comment to the ANPRM stated that keeping written records of equipment cleaning and use, including the date, product, and lot number of each batch processed, would be burdensome compared to the benefits it would provide, particularly when equipment is cleaned after each use. The comment added that manufacturers can modify their production records to note which machines they used.

We disagree with the comment. Written records will help you to ensure that all cleaning operations are performed correctly and, if problems do occur with the production of a product, will help you determine whether those