§ 111.210 What must the master manufacturing record include?

The master manufacturing record must include:

(a) The name of the dietary supplement to be manufactured and the strength, concentration, weight, or measure of each dietary ingredient for each batch size;

(b) A complete list of components to be used;

(c) An accurate statement of the weight or measure of each component to be used;

(d) The identity and weight or measure of each dietary ingredient that will be declared on the Supplement Facts label and the identity of each ingredient that will be declared on the ingredients list of the dietary supplement;

(e) A statement of any intentional overage amount of a dietary ingredient;

(f) A statement of theoretical yield of a manufactured dietary supplement expected at each point, step, or stage of the manufacturing process where control is needed to ensure the quality of the dietary supplement, and the expected yield when you finish manufacturing the dietary supplement, including the maximum and minimum percentages of theoretical yield beyond which a deviation investigation of a batch is necessary and material review is conducted and disposition decision is made;

(g) A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label;

(h) Written instructions, including the following:

(1) Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record;

(2) Procedures for sampling and a cross-reference to procedures for tests or examinations;

(3) Specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.

(i) Such specific actions must include verifying the weight or measure of any component and verifying the addition of any component; and

(ii) For manual operations, such specific actions must include:

(A) One person weighing or measuring a component and another person verifying the weight or measure; and

(B) One person adding the component and another person verifying the addition.

(4) Special notations and precautions to be followed; and

(5) Corrective action plans for use when a specification is not met.

Subpart I—Production and Process Control System: Requirements for the Batch Production Record

§ 111.255 What is the requirement to establish a batch production record?

(a) You must prepare a batch production record every time you manufacture a batch of a dietary supplement;

(b) Your batch production record must include complete information relating to the production and control of each batch;

(c) Your batch production record must accurately follow the appropriate master manufacturing record and you
§ 111.260 What must the batch record include?

The batch production record must include the following:

(a) The batch, lot, or control number:
   (1) Of the finished batch of dietary supplement; and
   (2) That you assign in accordance with §111.415(f) for the following:
      (i) Each lot of packaged and labeled dietary supplement from the finished
          batch of dietary supplement;
      (ii) Each lot of dietary supplement, from the finished batch of dietary sup-
           plement, that you distribute to another person for packaging or labeling;
   (b) The identity of equipment and processing lines used in producing the
       batch;
   (c) The date and time of the maintenance, cleaning, and sanitizing of the
       equipment and processing lines used in producing the batch, or a cross-ref-
       erence to records, such as individual equipment logs, where this information
       is retained;
   (d) The unique identifier that you assigned to each component (or, when ap-
       plicable, to a product that you receive from a supplier for packaging or label-
       ing as a dietary supplement), packaging, and label used;
   (e) The identity and weight or measure of each component used;
   (f) A statement of the actual yield and a statement of the percentage of
       theoretical yield at appropriate phases of processing;
   (g) The actual results obtained during any monitoring operation;
   (h) The results of any testing or examination performed during the batch
       production, or a cross-reference to such results;
   (i) Documentation that the finished dietary supplement meets specifications
       established in accordance with §111.70(e) and (g);
   (j) Documentation, at the time of performance, of the manufacture of the
       batch, including:
      (1) The date on which each step of the master manufacturing record was per-
          formed; and
      (2) The initials of the persons performing each step, including:
         (i) The initials of the person responsible for weighing or measuring each
             component used in the batch;
         (ii) The initials of the person responsible for verifying the weight or mea-
              sure of each component used in the batch;
         (iii) The initials of the person responsible for adding the component to the
              batch; and
         (iv) The initials of the person responsible for verifying the addition of com-
              ponents to the batch;
   (k) Documentation, at the time of performance, of packaging and labeling
       operations, including:
      (1) The unique identifier that you assigned to packaging and labels used,
          the quantity of the packaging and labels used, and, when label reconcili-
          ation is required, reconciliation of any discrepancies between issuance and use
          of labels;
      (2) An actual or representative label, or a cross-reference to the physical lo-
          cation of the actual or representative label specified in the master manufac-
          turing record; and
   (3) The results of any tests or examinations conducted on packaged and la-
       beled dietary supplements (including repackaged or relabeled dietary supple-
       ments), or a cross-reference to the physical location of such results;
      (1) Documentation at the time of performance that quality control person-
          nel:
         (1) Reviewed the batch production record, including:
            (i) Review of any monitoring operation required under subpart E of this
                part; and
            (ii) Review of the results of any tests and examinations, including tests and
                examinations conducted on components, in-process materials, finished
                batches of dietary supplements, and packaged and labeled dietary supple-
                ments;
            (2) Approved or rejected any reprocessing or repackaging; and
         (3) Approved and released, or rejected, the batch for distribution, in-
             cluding any reprocessed batch; and