Food and Drug Administration, HHS

§ 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 refer 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.