Food and Drug Administration, HHS

§ 111.205 What is the requirement to establish a master manufacturing record?

(a) You must prepare and follow a written master manufacturing record for each unique formulation of dietary supplement that you manufacture, and for each batch size, to ensure uniformity in the finished batch from batch to batch.

(b) The master manufacturing record must:

(b)(1) Be written and developed in accordance with the provisions of this subpart.

(b)(2) Be a record that includes:

(i) The characteristics of the finished batch, including but not limited to:

(A) The formula or formulation of the dietary supplement;

(B) The process used to manufacture the dietary supplement;

(C) The equipment used to manufacture the dietary supplement;

(D) The conditions under which the dietary supplement was manufactured;

(E) The quality control tests and procedures that were used to verify the quality of the dietary supplement;

(F) The results of the quality control tests and procedures;

(G) The special handling necessary to maintain the quality of the dietary supplement;

(ii) The process used to manufacture the dietary supplement, including:

(A) The ingredients used in the manufacture of the dietary supplement;

(B) The order in which the ingredients were added to the manufacturing process;

(C) The amount of each ingredient used;

(D) The process used to mix the ingredients; and

(E) The process used to package and label the dietary supplement;

(iii) The results of the quality control tests and procedures;

(iv) The special handling necessary to maintain the quality of the dietary supplement;

(b)(3) Be updated and maintained throughout the manufacturing process.

Subpart H—Production and Process Control System: Requirements for the Master Manufacturing Record

§ 111.170 What requirements apply to rejected components, packaging, and labels, and to rejected products that are received for packaging or labeling as a dietary supplement?

You must clearly identify, hold, and control under a quarantine system for appropriate disposition any component, packaging, and label, and any product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations.

§ 111.180 Under this subpart G, what records must you make and keep?

(a) You must make and keep the following records:

(1) Written procedures for fulfilling the requirements of this subpart.

(2) Receiving records (including records such as certificates of analysis, suppliers’ invoices, and suppliers’ guarantees) for components, packaging, and labels and for products that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier); and

(3) Documentation that the requirements of this subpart were met.

(i) The person who performs the required operation must document, at the time of performance, that the required operation was performed.

(ii) The documentation must include:

(A) The date that the components, packaging, labels, or products that you receive for packaging or labeling as a dietary supplement were received;

(B) The initials of the person performing the required operation;

(C) The results of any tests or examinations conducted on components, packaging, or labels, and of any visual examination of product that you receive for packaging or labeling as a dietary supplement; and

(D) Any material review and disposition decision conducted on components, packaging, labels, or products that you receive for packaging or labeling as a dietary supplement.