Audit to CSQ Code: Manufacturing of Cannabis Dietary Supplements with 21 CFR 111 Addendum

Overview: This document provides supporting information for the management and certification of CSQ Manufacturing of Cannabis Dietary Supplements with 21 CFR 111 Addendum. The completion of the Manufacturing of Cannabis Dietary Supplements with 21 CFR 111 Addendum will allow Cannabis Dietary Supplement operations to be compliant with certain states that require it, like Maryland.

1. Auditing Process:

Scheduling: Scheduling the dual audit will be done by the chosen Certification Body (CB). The Manufacturing of Cannabis Dietary Supplements with 21 CFR 111 Addendum audit will be scheduled in the CSQ database.

Auditor Selection: The Certification Body (CB) will select the auditor that is approved for Dietary Supplements.

Duration: The 21 CFR 111 Addendum will add approximately 4 hours (half day) to the audit duration.

Audit Report: Auditors will provide two reports:

1. CSQ Manufacturing of Cannabis Dietary Supplements
    a. Uploaded in CSQ Database
2. 21 CFR 111 Addendum
    a. Provided in Excel via email

Scoring: Scoring for the 21 CFR 111 Addendum will be Pass/Fail. Any and all non-conformances will need to be corrected with objective corrective actions completed within 30 days for a passing score. Any critical findings during the audit will be an automatic failure and the site will need to be reaudited.

Corrective Actions: All non-conformities identified in the 21 CFR 111 Addendum, both minor and major, must be addressed by the location following the rules outlined in the CSQ Certification Program Requirements, Part 2, Section 4.2.

Certification: After the site has passed the combined Manufacturing of Cannabis Dietary Supplements and 21 CFR 111 Addendum audits they will be awarded one certificate stating both. Within the CSQ Manufacturing of Cannabis Dietary Supplements Certificate will be a note stating the site has also passed the 21 CFR 111 Addendum.

2. Checklist:

111.10: Personnel Hygiene

If you work in an operation during which adulteration of the component, dietary supplement, or contact surface could occur, you must use hygienic practices to the extent necessary to protect against such contamination of components, dietary supplements, or contact surfaces. This includes:

a. Not drinking beverages (including water).
b. Taking any other precautions necessary to protect against contamination with microorganisms, filth, or any other extraneous materials including perspiration and medicines applied to the skin.

111.15(a): Grounds

You must keep the grounds of your physical plant in a condition that protects against the contamination of components, dietary supplements, or contact surfaces. The methods for adequate ground maintenance include:

a. Adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, dietary supplements or contact surfaces are exposed.
b. If your plant grounds are bordered by grounds not under your control, and if those grounds are not maintained in the manner described in this section, you must exercise care in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination.

111.15(b): Water Supply

Water that is used in a manner such that the water may become a component of the dietary supplement, e.g., when such water contacts components, dietary supplements, or any contact surface, must, at a minimum, comply with applicable Federal, State, and local requirements and not contaminate the dietary supplement.

a. The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to:
    i. carry sufficient amounts of water to required locations throughout the plant.
    ii. properly convey sewage and liquid disposable waste from your physical plant

111.15(c): Sewage and trash disposal

a. You must dispose of sewage into an adequate sewage system or through other adequate means.
b. You must convey, store and dispose of trash to control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.

111.27: Single-service articles

Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be:

a. Stored in appropriate containers
b. Handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary supplements, or any contact surface.

111.30: Equipment

For any automated, mechanical, or electronic equipment that you use to manufacture, package, label, or hold a dietary supplement, you must:

a. Establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that any changes to the manufacturing, packaging, labeling, holding, or other operations are approved by quality control personnel
b. Establish and use appropriate controls to ensure that the equipment functions in accordance with its intended use. These controls must be approved by quality control personnel.

111.83: Reserve Samples

a. You must collect and hold reserve samples of each lot of packaged and labeled dietary supplements that you distribute.
b. The reserve samples must:
    i. Be held using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which it is distributed for packaging and labeling elsewhere;
    ii. Be identified with the batch, lot, or control number;
    iii. Be retained for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve sample, for use in appropriate investigations;
    iv. Consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications.

111.130: Quality control operations - returned dietary supplements.

Quality control operations for returned dietary supplements must include:

a. Conducting any required material review and making any required disposition decision; including:
    i. Determining whether tests or examination are necessary to determine compliance with product specifications established;
    ii. Reviewing the results of any tests or examinations that are conducted to determine compliance with product specifications established;
b. Approving or rejecting any salvage and redistribution of any returned dietary supplement;
c. Approving or rejecting any reprocessing of any returned dietary supplement;
d. Determining whether the reprocessed dietary supplement meets product specifications and either approving for release, or rejecting, any returned dietary supplement that is reprocessed.

111.205: Master manufacturing record

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. The master manufacturing record must:

a. Identify specifications for the 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;
b. Establish controls and procedures to ensure that each batch of dietary supplement that you manufacture meets the specifications identified.

111.210: Master manufacturing records

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:
    i. 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;
    ii. Procedures for sampling and a cross-reference to procedures for tests or examinations;
    iii. 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.
iv. Special notations and precautions to be followed; and
v. Corrective action plans for use when a specification is not met

111.255: Batch production record

You must prepare a batch production record every time you manufacture a batch of a dietary supplement. The batch production record must:

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 must perform each step in the production of the batch; and
d. You must make and keep batch production records in accordance with subpart P of this part.

111.260: Batch production record

The batch production record must include the following:

a. The batch, lot, or control number:
    i. Of the finished batch of dietary supplement; and
    ii. Each lot of packaged and labeled dietary supplement from the finished batch of dietary supplement;
    iii. Each lot of dietary supplement, from the finished batch of dietary supplement, 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-reference to records, such as individual equipment logs, where this information is retained;
d. The unique identifier that you assigned to each component (or, when applicable, to a product that you receive from a supplier for packaging or labeling 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:
    i. The date on which each step of the master manufacturing record was performed; and
    ii. The initials of the persons performing each step, including:
        1. The initials of the person responsible for weighing or measuring each component used in the batch;
        2. The initials of the person responsible for verifying the weight or measure of each component used in the batch;
        3. The initials of the person responsible for adding the component to the batch; and
        4. The initials of the person responsible for verifying the addition of components to the batch;
k. Documentation, at the time of performance, of packaging and labeling operations, including:
    i. The unique identifier that you assigned to packaging and labels used, the quantity of the packaging and labels used, and, when label reconciliation is required, reconciliation of any discrepancies between issuance and use of labels;
    ii. An actual or representative label, or a cross-reference to the physical location of the actual or representative label specified in the master manufacturing record; and
    iii. The results of any tests or examinations conducted on packaged and labeled dietary supplements (including repackaged or relabeled dietary supplements), or a cross-reference to the physical location of such results;
l. Documentation at the time of performance that quality control personnel:
    i. Reviewed the batch production record, including:
        1. Review of any monitoring operation required under subpart E of this part; and
        2. 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 supplements;
    ii. Approved or rejected any reprocessing or repackaging; and
    iii. Approved and released, or rejected, the batch for distribution, including any reprocessed batch; and

iv. Approved and released, or rejected, the packaged and labeled dietary supplement, including any repackaged or relabeled dietary supplement.

m. Documentation at the time of performance of any required material review and disposition decision.

n. Documentation at the time of performance of any reprocessing.

111.465: Reserve Samples

a. You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes:
   i. Holding the reserve samples under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions; and
   ii. Using the same container-closure system in which the packaged and labeled dietary supplement is distributed, or if distributing dietary supplements to be packaged and labeled, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which you distribute the dietary supplement for packaging and labeling elsewhere.
      1. You must retain reserve samples for 1 year past the shelf life date (if shelf life dating is used), or for 2 years from the date of distribution of the last batch of dietary supplements associated with the reserve samples, for use in appropriate investigations.