Good agricultural and collection practices and good manufacturing practices for botanical materials

Company Information

Company name			
Street Address			
City/State		**Country**	
Contact name		**Contact phone**	
Contact email		**Company website**	
Botanical material operation	<Describe the scope of the botanical material operation addressed by this form>		

This form is for use in conjunction with Section 10 Recommendations for Dietary Ingredient Processors, AHPA Good agricultural collection practices and good manufacturing practices for botanical materials. Supporting information for specific elements can be attached to this form.

Section 10 consists of recommendations to be considered; they are not legal or regulatory requirements except as noted. Facilities that manufacture[1], pack, or hold dietary *supplements* are subject to the regulations in 21 CFR Part 111, while those that manufacture, pack, or hold dietary *ingredients* are technically subject only to the requirements of Part 117. However, in order to ensure their own compliance with the requirements of Part 111, dietary supplement manufacturers often expect their ingredient suppliers to go above and beyond the basic requirements set forth in Part 117, particularly with respect to raw material controls, process controls, recordkeeping, and general quality systems management. Therefore, dietary ingredient processors that do not follow the full requirements of Part 117 may want to consider implementing the additional recommendations set forth below.

Dietary ingredient processors may be required to comply with the provisions of 21 CFR Part 111 under two circumstances.[2]

1. Under U.S. regulations, a dietary ingredient processor is considered to be a dietary supplement manufacturer, and therefore subject to Part 111, if the dietary ingredient is packaged as a dietary supplement without further processing.
2. In an effort to ensure product quality, dietary supplement manufacturers and packagers may require their suppliers to comply with Part 111 as a condition of purchase for the dietary ingredient.

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[1] "To manufacture" in this context includes "to process," and vice versa. U.S. food regulations generally do not distinguish between "processing" and "manufacturing"; see the definition of "manufacturing/processing." However, there is a subtle but important distinction between "manufacturing/processing" (as used in FDA food regulations) and "processing" (as used in U.S. law). (See the definition of "processed food" for more information.)

[2] Firms that comply with Part 111 are exempt from Part 117 Subparts C and G; see Appendix 4 for more information.

D10 Recommendations for Dietary Ingredient Processors		Assessment[1]			
Element	**Description**	**N/A**	**Meet**	**Partial**	**Deficient**
DI10.2 Component controls					
DI10.2 i)	Appropriate specifications are established for each component (including botanical ingredients, other ingredients, processing aids, packaging materials, and labels).				
Comments:					
DI10.2 ii)	Incoming shipments of components are assigned a lot number and quarantined pending sampling, inspection, testing, and disposition.				
Comments:					
DI10.2 iii)	Incoming shipments of components are properly labeled and examined for damage or contamination.				
Comments:					
DI10.2 iv)	Components are sampled in accordance with appropriate sampling plans and procedures to ensure representative samples are obtained.				
Comments:					
DI10.2 v.1-3)	Appropriate steps are taken to ensure each component lot meets its established specifications.				
Comments:					
DI10.2 vi)	All documentation and test results for a lot should be reviewed before the disposition of the lot (e.g., approval or rejection) is decided.				
Comments:					
DI10.2 vii)	Approved component lots are stored under appropriate conditions of temperature, humidity, and light.				
Comments:					
DI10.2 viii)	Rejected components are segregated from other components.				
Comments:					
DI10.2 ix)	A retention sample of each component lot is kept for an appropriate length of time or as required by regulation.				
Comments:					
DI10.2 x)	All documents related to the lot are appropriately identified and are kept for an appropriate length of time or as required by regulation.				
Comments:					

D10 Recommendations for Dietary Ingredient Processors		Assessment[1]			
Element	**Description**	**N/A**	**Meet**	**Partial**	**Deficient**
DI10.2 xi)	For each component lot, an inventory control log or other recordkeeping system is used to document all inventory transactions related to the lot.				
Comments:					
DI10.3 Processing operations and finished product controls					
DI10.3 i.1-8)	For each manufacturing and packaging process, comprehensive processing specifications are established and documented that ensure finished product quality specifications (Master Manufacturing Record or MMR).				
Comments:					
DI10.3 iii.1-13)	For each cycle of manufacturing or packaging, a record of the processing of the batch document is created (Batch Production Record or BPR).				
Comments:					
DI10.3 iv)	The allocation of components or issuance of labels for use in manufacturing or packaging is appropriately controlled.				
Comments:					
DI10.3 v)	Finished product batches are sampled in accordance with appropriate sampling plans and procedures.				
Comments:					
DI10.3 vi.1-3)	Appropriate steps are taken to ensure each finished product batch meets its established specifications.				
Comments:					
DI10.3 vii)	All documentation and test results for a batch is reviewed before the disposition of the batch.				
Comments:					
DI10.3 viii)	Approved finished product batches are stored under appropriate conditions of temperature, humidity, and light.				
Comments:					
DI10.3 ix)	Rejected finished product batches are segregated from other finished products.				
Comments:					
DI10.3 x)	All documents related to the batch are appropriately identified and are kept for an appropriate length of time or as required by regulation.				
Comments:					

D10 Recommendations for Dietary Ingredient Processors		Assessment[1]			
Element	**Description**	**N/A**	**Meet**	**Partial**	**Deficient**
DI10.3 xi)	For each finished product batch, an inventory control log or other recordkeeping system is used to document all inventory transactions related to the batch.				
Comments:					
DI10.3 xii)	A retention sample of each finished batch is kept for an appropriate length of time or as required by regulation.				
Comments:					
DI10.4 Laboratory operations					
DI10.4 i)	Test methods are maintained in writing and are appropriately accurate, precise, specific, and suitable for their intended purpose.				
Comments:					
DI10.4 ii)	Appropriate analytical standards are used for laboratory testing.				
Comments:					
DI10.5 Personnel					
DI10.5 i)	Personnel are qualified by training or experience for the tasks to be performed.				
Comments:					
DI10.5 ii)	Personnel qualifications and training are documented and maintained on file.				
Comments:					
DI10.5 iii)	Personnel training includes: 1. Health, safety, and environmental protection procedures 2. Personal hygienic practices 3. Food safety procedures 4. Good manufacturing practices 5. Job specific information				
Comments:					
DI10.6 Equipment					
DI10.6 i)	Processing, packaging, and testing equipment is suitable for its intended purpose and capable of operating satisfactorily.				
Comments:					
DI10.6 ii)	Processing, packaging, and testing equipment is properly cleaned, and sanitized where appropriate.				
Comments:					

D10 Recommendations for Dietary Ingredient Processors		Assessment[1]			
Element	**Description**	**N/A**	**Meet**	**Partial**	**Deficient**
DI10.6 iii)	Processing, packaging, and testing equipment is properly maintained in accordance with the equipment manufacturer's instructions.				
Comments:					
DI10.6 iv)	Processing, packaging, and testing equipment is properly verified or calibrated at suitable frequencies.				
Comments:					
DI 1.7 Quality management					
DI10.7 i)	Appropriate quality assurance practices are implemented to ensure product quality and GMP compliance.				
Comments:					
DI10.7 ii)	Standard operating procedures are written for manufacturing, packaging, laboratory, warehousing, and quality management operations.				
Comments:					
DI10.7 iii)	Records are made contemporaneously of all activities performed in the facility that may impact product quality or GMP compliance and are maintained for an appropriate length of time or as required by regulation.				
Comments:					
DI10.7 iv)	A system for receiving, documenting, and investigating product-related customer complaints has been implemented, including but not limited to adverse events.				
Comments:					
DI10.7 v)	A system should be implemented for receiving, quarantining, and determining the disposition of returned goods.				
Comments:					
DI10.7 vi)	Quality management personnel approve or reject all specifications, controls, tests, examinations, standard operating procedures, master manufacturing records, labels, and other documents or procedures that may affect the quality of the botanical product.				
Comments:					
DI10.7 vi)	Quality management personnel approve or reject all deviations from these procedures, including any reprocessing or repackaging.				
Comments:					

D10 Recommendations for Dietary Ingredient Processors		**Assessment[1]**			
Element	**Description**	**N/A**	**Meet**	**Partial**	**Deficient**
DI10.7 vii)	Quality management personnel approve or reject all component lots, finished product batches, and returned goods.				
Comments:					
DI10.7 viii)	Quality management personnel review records of facility and equipment cleaning and sanitization; pest control; equipment verifications and calibrations; employee training; sampling records; and customer complaints.				
Comments:					
DI10.7 ix)	Quality management personnel approve or reject all changes to facilities, equipment, specifications, controls, tests, examinations, standard operating procedures, master manufacturing records, labels, and any other changes that may affect the quality or GMP compliance of the botanical product.				
Comments:					
[1] Assessments are used to indicate the degree of compliance or adherence to the specific element. N/A = This element is not applicable to the operation Meet = Fully compliant or adherent to the element Partial = Greater than 50% compliant to the element Deficient = Less than 50% or no compliance to the element					

I attest that all the information contained in this form is correct to the best of my knowledge.

Signature:_____ Date:_____