Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy
Pharmaceutical Processor Inspection Report

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Pharmaceutical Processor Name:		**Inspection Type:**	
Pharmaceutical Processor Permit Number:		**Inspection Results:**	
Legal Business Name:		**Date of Last Inspection:**	
Doing Business As (DBA):		**Day 1:**	
Address:		**Start Time: 24-hour format (13:00)**	
City:		**End Time: 24-hour format (13:00)**	
City:		**Day 2:**	
State:		**Start Time: 24-hour format (13:00)**	
Zip Code:		**End Time: 24-hour format (13:00)**	
Designated Health Service Area:		**Inspector Name:**	
Telephone number:		**Observer Name/Affiliation (if applicable):**	
Toll free number:		**Pharmacist on Duty:**	
Fax number:		**Pharmacist on Duty License Number:**	
Email address:		**Inspection Emailed To (person):**	
Website:		**Inspection Emailed To (email address):**	

Hours of Operation	**Is facility open 24/7?**		
	Open		**Closed**
	Start Time: (24-hour format hh:mm)	**End Time: (24-hour format hh:mm)**	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc.)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date

Personnel

Personnel present at the time of inspection:

Pharmacists:		Pharmacist:Pharmacy Technician Ratio			
Pharmacy Technicians:		Pharmacy Interns:		Unlicensed Staff:	

List all personnel employed by the processor (Attach list if additional space is required):

Position	Name	License Number	Activity	Describe Degree or Experience - Indicate if training completed (Y/N)	
Pharmacist-in-Charge					

Inspector Notes:

Personnel					
Position	Name	License Number	Activity	Describe Degree or Experience - Indicate if training completed (Y/N)	

Permit & Personnel			
		Result	**Notes**
	Processor Permit		**§54.1-3442.6 & 18VAC110-60-110**
	No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor.. **[§54.1-3342.6 & 18 VAC 110-60-110]** .		
	Every pharmaceutical processor shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.		
	Employee Licenses & Registration 18 VAC 110-60-170		**18 VAC 110-60-170**
	A pharmacist with a current, unrestricted license issued by the board, practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.		
Operations			
	Security Requirements		**18 VAC 110-60-240**
	The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, cannabidiol oil, or THC-A oil.		
	A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor.		
	The installation and the device shall be based on accepted alarm industry standards and shall be subject to the following conditions:		
	1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		
	2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	3. The device shall fully protect the **entire processor facility** and shall be capable of detecting breaking by any means when activated.		
	4. The device shall include a **duress alarm, a panic alarm**, and **automatic voice dialer.**		
	5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.		
	A pharmaceutical processor shall keep the outside perimeter of the premises well-lit.		
	A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.		

		Result	Notes
	1. The processor shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil, or THC-A oil sales areas and any other area where Cannabis plants, seeds, extracts, cannabidiol oil, or THC-A oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility.		
	2. The video system shall have:		
	a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message.		
	b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded).		
	c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture.		
	d. The ability to remain operational during a power outage.		
	3. All video recording shall allow for the exporting of still images in an industry standard image format.		
	4. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system.		
	5. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility.		
	6. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days.		
	7. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.		
	The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.		
	All security equipment shall be maintained in good working order and shall be tested no less than two times per year.		
	A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board.		
	A processor shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor.		
	The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.		
	Storage & Handling		**18 VAC 110-60-250**
	A pharmaceutical processor shall:		
	1. Have storage areas that provide adequate conditions for the cultivation of Cannabis, and the production and dispensing of cannabidiol oil or THC-A oil:		

		Result	Notes
	a. Lighting		
	b. Sanitation		
	c. Ventilation		
	d. Space		
	e. Equipment		
	f. Temperature as defined in 18 VAC 110-60-10		
	g. Humidity as defined in 18 VAC 110-60-10		
	<table><tr><th>Room or Phase</th><th>Temperature</th><th>Humidity</th></tr><tr><td>Mother room</td><td>65 - 75°</td><td>50% - 60%</td></tr><tr><td>Nursery phase</td><td>71 - 85° F</td><td>65% - 75%</td></tr><tr><td>Vegetation phase</td><td>71 - 85° F</td><td>55% - 65%</td></tr><tr><td>Flower/harvest phase</td><td>71 - 85° F</td><td>55% - 60%</td></tr><tr><td>Drying/extraction rooms</td><td>< 75° F</td><td>55% - 60%</td></tr></table>		
	2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil is destroyed.		
	3. Be maintained in a clean, sanitary, and orderly condition.		
	4. Be free from infestation by insects, rodents, birds, or vermin of any kind.		
	A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments.		
	Policies & Procedures		**18 VAC 110-60-250**
	The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabidiol oil or THC-A oil. These shall include policies and procedures that:		
	1. Restrict movement between compartments.		
	2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility.		
	3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil.		
	4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.		
	The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil.		
	Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories.		
	Pharmaceutical processors shall include in their written policies and procedures, a process for the following:		

		Result	Notes
	1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. Such process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to remove defective or potentially defective cannabidiol oil or THC-A oil from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;		
	2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;		
	3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and		
	4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil product is used first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.		
	Record Keeping Requirements		**18 VAC 110-60-260**
	If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabidiol oil or THC-A oil, the pharmaceutical processor shall use a system that:		
	1. Guarantees the confidentiality of the information contained therein.		
	2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.		
	3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.		
	Production		
	Labeling of Batch of CBD or THC-A Products		**18 VAC 110-60-290**
	Cannabidiol oil or THC-A oil produced shall not be adulterated and shall be:		
	1. Processed, packaged, and labeled according to the Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR Part 111.		
	2. Labeled with :		
	a. The name and address of the pharmaceutical processor.		
	b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285.		
	c. A unique serial number that will match the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate.		
	d. The date of testing and packaging.		
	e. The expiration date based on stability testing.		
	f. The quantity of cannabidiol oil or THC-A oil contained in the batch.		
	g. A terpenes profile and a list of all active ingredients, including:		
	i. tetrahydrocannabinol (THC).		

		Result	Notes
	ii. tetrahydrocannabinol acid (THCA). iii. cannabidiol (CBD). iv. cannabidiolic acid (CBDA).		
	h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis.		
	Laboratory Requirements & Testing		**18 VAC 110-60-300**
	No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabidiol oil or THC-A oil unless such laboratory:		
	1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and		
	2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.		
	Dispensing		
	Labeling of Dispensed CBD or THC-A Oil		**18 VAC 110-60-310**
	The pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:		
	1. A serial number assigned to the dispensing of the oil.		
	2. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285 and its strength..		
	3. The serial number as assigned to the oil during production.		
	4. The date of dispensing the cannabidiol oil or THC-A oil.		
	5. The quantity of cannabidiol oil or THC-A oil contained therein.		
	6. A terpenes profile and a list of all active ingredients, including: a. Tetrahydrocannabinol (THC). b. Tetrahydrocannabinol acid (THC-A). c. Cannabidiol (CBD). d. Cannabidiolic acid (CBDA)		
	7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and chemical residue analysis.		
	8. The name and registration number of the registered patient.		
	9. The name and registration number of the certifying practitioner.		
	10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner.		
	11. The name or initials of the dispensing pharmacist.		
	12. Name and address, and telephone number of the pharmaceutical processor.		
	13. Any necessary cautionary statement.		
	14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.		

		Result	Notes
	A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.		
Quality Assurance Program			
	Dispensing Error Review, Reporting, Quality Assurance Program		**18 VAC 110-60-320**
	A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors.		
	A pharmaceutical processor shall distribute the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor.		
	Such policies and procedures shall include:		
	1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient.		
	2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.		

Permit & Personnel			
		Result	**Notes**
	Processor Permit		**§54.1-3442.6**
	No person shall operate a pharmaceutical processor without first obtaining a permit from the Board.		
	Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.		
	Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.		
	In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience: (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the Board or who has at least two years of experience cultivating plants (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.		
	No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor.. **[§54.1-3342.6 & 18 VAC 110-60-110]**		
	Every pharmaceutical processor shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.		
	Employee Licenses & Registration 18 VAC 110-60-170		**18 VAC 110-60-170**
	A pharmacist with a current, unrestricted license issued by the board, practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.		
	A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed.		
	A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and who has had at least two years of experience practicing as a pharmacy technician may perform the following duties under supervision of a pharmacist: 1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system. 2. The preparation of labels for dispensing the oils or patient information. 3. The removal of the oil to be dispensed from inventory. 4. The measuring of the oil to be dispensed. 5. The packaging and labeling of the oil to be dispensed and the repackaging thereof; 6. The stocking or loading of devices used in the dispensing process. 7. The selling of the oil to the registered patient, parent, or legal guardian. 8. The performance of any other task restricted to pharmacy technicians by the board's regulations.		
	A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils as authorized by the PIC or as otherwise authorized in law.		

		Result	Notes
	A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.		
	A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician, but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil as authorized by the PIC.		
	A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, cannabidiol oil, and THC-A oil and ensure quality of the dispensed oils.		
	At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.		
	No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.		
	No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor unless such license or registration has been reinstated and is current and unrestricted.		
	Employee Training		**18 VAC 110-60-180**
	All employees of a pharmaceutical processor shall complete training prior to the employee commencing work at the pharmaceutical processor. At a minimum, the training shall be in the following areas:		
	1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil, and THC-A oil.		
	2. Procedures and instructions for responding to an emergency.		
	3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality.		
	4. Developments in the field of the medical use of cannabidiol oil or THC-A oil.		
	Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.		
	The PIC shall assure the continued competency of all employees through continuing in-service training that is provided at least annually, is designed to supplement initial training, and includes any guidance specified by the board.		
	The PIC shall be responsible for maintaining a written record documenting the initial and continuing training of all employees, which shall contain: 1. The name of the person receiving the training. 2. The dates of the training. 3. A general description of the topics covered. 4. The name of the person supervising the training. 5. The signatures of the person receiving the training and the PIC.		
	When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.		
	A pharmaceutical processor shall maintain the record documenting the employee training and make it available in accordance with regulations.		

		Result	Notes
	Pharmacy Technicians 18 VAC 110-20-190		**18 VAC 110-60-190**
	The ratio of pharmacy technicians to pharmacists on-duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed four pharmacy technicians to one pharmacist.		
	The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabidiol oil or THC-A oil resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who: 1. Is on duty where the pharmacy technician is performing routine cannabidiol oil or THC-A oil production or dispensing functions; and 2. Conducts in-process and final checks on the pharmacy technician's performance.		
	Pharmacy technicians shall not:		
	1. Counsel a registered patient or the patient's parent or legal guardian regarding cannabidiol oil, THC-A oil, or other drugs, either before or after cannabidiol oil or THC-A oil has been dispensed, or regarding any medical information contained in a patient medication record.		
	2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking.		
	3. Interpret the patient's clinical data or provide medical advice.		
	4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian.		
	5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.		
	PIC Responsibilities		**18 VAC 110-60-200**
	No person shall be PIC for more than one pharmaceutical processor at any time.		
	A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.		
	The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.		
	The pharmaceutical processor PIC shall be responsible for ensuring that:		
	1. Pharmacy technicians are registered and all employees are properly trained.		
	2. All record retention requirements are met.		
	3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, and THC-A oil are met.		
	4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed.		
	5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians:		
	a. Pharmaceutical processor permit.		
	b. Licenses for all pharmacists practicing at the pharmaceutical processor.		
	c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor.		
	6. Any other required filings or notifications are made on behalf of the processor as set forth in regulation.		

		Result	Notes
	When the PIC ceases practice at a pharmaceutical processor or no longer wishes to be designated as PIC, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the PIC.		
	An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board.		
	Prescription Monitoring Program		**§54.1-2521**
	Upon dispensing a covered substance, a dispenser of such covered substance shall submit a report to the Prescription monitoring program. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.		
	§54.1-2519: "Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.		

Operations			
		Result	Notes
	Processor Permit		**§54.1-3442.7 & 18 VAC 110-60-130**
	A pharmaceutical processor may begin cultivation upon being issued a permit by the Board. **[§54.1-3442.7]**		
	Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis.		
	Notification of Changes		**18 VAC 110-60-140**
	Prior to making any change to the pharmaceutical processor name, the pharmaceutical processor shall submit an application for such change to the board and pay the fee.		
	Any person wishing to engage in the acquisition of an existing pharmaceutical processor, change the location of an existing pharmaceutical processor, make structural changes to an existing pharmaceutical processor, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.		
	The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.		
	Cannabis shall not be moved to a new location until approval is granted by the inspector or board staff.		
	Closings, Going Out of Business, Change of Ownership		**18 VAC 110-60-150**
	At least 14 days prior to any change in ownership of an existing pharmaceutical processor, the owner shall notify the board of the pending change.		
	Upon any change in ownership of an existing pharmaceutical processor, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.		
	The previous owner shall be held responsible for assuring the proper and lawful transfer of records on the date of the transfer.		
	General Provisions		**18 VAC 110-60-210**
	The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor to: 1. Such persons whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties. 2. Such person who is a registered patient, parent, or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil is stored.		
	All pharmacists and pharmacy technicians shall, at all times while at the pharmaceutical processor, have their current license or registration available for inspection by the board or the board's agent.		
	While inside the pharmaceutical processor, all pharmaceutical processor employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor.		
	A pharmaceutical processor shall be open for registered patients, parents, or legal guardians to purchase cannabidiol oil or THC-A oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.		

		Result	Notes
	A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs.		
	If the pharmaceutical processor is, or will be, closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.		
	A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil and for disposal of the oils in a manner that renders them nonrecoverable.		
	The pharmaceutical processor shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy, which shall be available to the board or the board's agent upon request.		
	Prohibitions		**18 VAC 110-60-220**
	No pharmaceutical processor shall: 1. Cultivate Cannabis plants, produce, or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit. 2. Sell, deliver, transport, or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility. 3. Produce or manufacture cannabidiol oil or THC-A oil for use outside of Virginia. 4. Provide cannabidiol oil or THC-A oil samples.		
	No pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.		
	No pharmaceutical processor shall sell anything other than cannabidiol oil or THC-A oil products from the pharmaceutical processor.		
	A pharmaceutical processor shall not advertise cannabidiol oil or THC-A oil products, except it may post the following information on websites: 1. Name and location of the processor; 2. Contact information for the processor; 3. Hours and days the pharmaceutical processor is open for dispensing cannabidiol oil or THC-A oil products; 4. Laboratory results; 5. Product information and pricing; and 6. Directions to the processor facility.		
	No cannabidiol oil or THC-A oil shall be consumed on the premises of a pharmaceutical processor, except for emergency administration to a registered patient.		
	No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: **laboratory staff** may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.		
	Notwithstanding the requirements of 18 VAC 110-60-220 (F), an agent of the board, local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.		

		Result	Notes
	All persons who have been authorized, in writing, to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee, prior to entering the pharmaceutical processor.		
	1. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor. 2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor. 3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log, which shall include the date, time, and purpose of the visit, and that shall be available to the board. 4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.		
	No cannabidiol oil or THC-A oil shall be sold, dispensed, or distributed via a **delivery service** or any other manner outside of a pharmaceutical processor, except that a registered parent or legal guardian or an agent of the processor may deliver cannabidiol oil or THC-A oil to the registered patient or in accordance with 18VAC110-60-310 A.		
	Inventory Requirements 18 VAC 110-60-230		**18 VAC 110-60-230**
	Each pharmaceutical processor, prior to commencing business, shall:		
	1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil at the facility. The inventory shall include, at a minimum: A. Date of the inventory B. Summary of the inventory findings C. Name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory D. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory.		
	2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, which shall enable the facility to detect any diversion, theft, or loss in a timely manner.		
	Upon commencing business, each pharmaceutical processor and production facility shall conduct a **weekly** inventory of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil in stock. A. The weekly inventory shall include, at a minimum, B. Date of the inventory. C. Summary of the inventory findings. D. Name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory.		

		Result	Notes
	The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show: A. Date of sale B. Name of the pharmaceutical processor, registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold C. Address of such person D. Kind and quantity of cannabidiol oil or THC-A oil sold.		
	The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show		
	A. Date of sale or disposition.		
	B. Name of the pharmaceutical processor.		
	C. Name and address of the registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold.		
	D. Kind and quantity of cannabidiol oil or THC-A oil sold or disposed of.		
	E. Method of disposal.		
	A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC may choose, so long as it is not more than one year following the prior year's inventory.		
	All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.		
	Inventory records shall be maintained for **three years** from the date the inventory was taken.		
	Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.		
	Security Requirements		**18 VAC 110-60-240**
	A pharmaceutical processor shall **initially** cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the **first nine months** of operation.		
	Thereafter, the processor shall:		
	1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days.		
	2. Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation.		
	3. Maintain all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation.		
	4. Store all cut parts of Cannabis plants, extracts, cannabidiol oil, or THC-A oil in an approved safe or approved vault within the pharmaceutical processor.		
	Shall not sell cannabidiol oil or THC-A oil products when the pharmaceutical processor is closed.		
	5. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabidiol oil or THC-A oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil.		
	6. Keep all locks and security equipment in good working order.		
	7. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor.		
	8. Not allow keys to be left in the locks or accessible to nonpharmacists.		

		Result	Notes
	The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, cannabidiol oil, or THC-A oil.		
	A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor.		
	The installation and the device shall be based on accepted alarm industry standards and shall be subject to the following conditions:		
	1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		
	2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	3. The device shall fully protect the **entire processor facility** and shall be capable of detecting breaking by any means when activated.		
	4. The device shall include a **duress alarm, a panic alarm**, and **automatic voice dialer.**		
	5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.		
	A pharmaceutical processor shall keep the outside perimeter of the premises well-lit.		
	A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.		
	1. The processor shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil, or THC-A oil sales areas and any other area where Cannabis plants, seeds, extracts, cannabidiol oil, or THC-A oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility.		
	2. The video system shall have:		
	a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message.		
	b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded).		
	c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture.		
	d. The ability to remain operational during a power outage.		
	3. All video recording shall allow for the exporting of still images in an industry standard image format.		
	4. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system.		

		Result	Notes
	5. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility.		
	6. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days.		
	7. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.		
	The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.		
	All security equipment shall be maintained in good working order and shall be tested no less than two times per year.		
	A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board.		
	A processor shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor.		
	The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.		
	Storage & Handling		**18 VAC 110-60-250**
	A pharmaceutical processor shall:		
	1. Have storage areas that provide adequate conditions for the cultivation of Cannabis, and the production and dispensing of cannabidiol oil or THC-A oil:		
	a. Lighting		
	b. Sanitation		
	c. Ventilation		
	d. Space		
	e. Equipment		
	f. Temperature as defined in 18 VAC 110-60-10		
	g. Humidity as defined in 18 VAC 110-60-10		
	<table><tr><th>Room or Phase</th><th>Temperature</th><th>Humidity</th></tr><tr><td>Mother room</td><td>65 - 75°</td><td>50% - 60%</td></tr><tr><td>Nursery phase</td><td>71 - 85° F</td><td>65% - 75%</td></tr><tr><td>Vegetation phase</td><td>71 - 85° F</td><td>55% - 65%</td></tr><tr><td>Flower/harvest phase</td><td>71 - 85° F</td><td>55% - 60%</td></tr><tr><td>Drying/extraction rooms</td><td>< 75° F</td><td>55% - 60%</td></tr></table>		
	2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil is destroyed.		
	3. Be maintained in a clean, sanitary, and orderly condition.		
	4. Be free from infestation by insects, rodents, birds, or vermin of any kind.		

		Result	Notes
	A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments.		
	The processor shall:		
	1. Store all Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss.		
	2. Make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation.		
	3. Return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day.		
	If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, inside an area or building that affords adequate security.		
	Policies & Procedures		**18 VAC 110-60-250**
	The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabidiol oil or THC-A oil. These shall include policies and procedures that:		
	1. Restrict movement between compartments.		
	2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility.		
	3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil.		
	4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.		
	The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil.		
	Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories.		
	Pharmaceutical processors shall include in their written policies and procedures, a process for the following:		
	1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. Such process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to remove defective or potentially defective cannabidiol oil or THC-A oil from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;		
	2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;		

		Result	Notes
	3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and		
	4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil product is used first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.		
	Record Keeping Requirements		**18 VAC 110-60-260**
	If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabidiol oil or THC-A oil, the pharmaceutical processor shall use a system that:		
	1. Guarantees the confidentiality of the information contained therein.		
	2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.		
	3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.		
	All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of **three** years and shall be made available to the board upon request.		
	Reportable Events & Security		**18 VAC 110-60-270**
	Upon becoming aware of (i) diversion, theft, loss, or discrepancies identified during inventory; (ii) unauthorized destruction of any cannabidiol oil or THC-A oil; or (iii) any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law-enforcement authorities and the board.		
	A pharmacist or processor shall provide the notice required by 18 VAC 110-20-270 (A) to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabidiol oil or THC-A oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified.		
	A pharmacist or processor shall make such notice no later than 24 hours after discovery of the event.		
	A pharmacist or pharmaceutical processor shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following: 1. An alarm activation or other event that requires a response by public safety personnel. 2. A breach of security. 3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours. 4. Corrective measures taken, if any.		

		Result	Notes
	A pharmacist or pharmaceutical processor shall immediately notify the board of an employee convicted of a felony or any offense referenced in § 54.1-3442.6 of the Code of Virginia. *§54.1-3442.6 (G) No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor.*		

Cultivation			
		Result	Notes
	Cultivation & Production		**18 VAC 110-60-280**
	No cannabidiol oil or THC-A oil shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.		
	Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.		
	Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.		
	Registration of Products		**18 VAC 110-60-285**
	A pharmaceutical processor shall assign a brand name to each product of cannabidiol oil or THC-A oil.		
	The pharmaceutical processor shall register each brand name with the board, on a form prescribed by the board, prior to any dispensing.		
	The pharmaceutical processor shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including: 1. Tetrahydrocannabinol (THC). 2. Tetrahydrocannabinol acid (THCA). 3. Cannabidiols (CBD). 4. Cannabidiolic acid (CBDA).		
	A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within 18 VAC 110-60-285 (A) within a range of 90% to 110%.		

Production			
		Result	Notes
	Concentration & Stability of THC-A Oil		**§54.1-3442.7**
	The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling.		
	A pharmaceutical processor shall :		
	1. Ensure that such concentration in any THC-A onsite is within such range		
	2. Establish a stability testing schedule of THC-A oil.		
	Labeling of Batch of CBD or THC-A Products		**18 VAC 110-60-290**
	Cannabidiol oil or THC-A oil produced shall not be adulterated and shall be:		
	1. Processed, packaged, and labeled according to the Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR Part 111.		
	2. Labeled with :		
	a. The name and address of the pharmaceutical processor.		
	b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285.		
	c. A unique serial number that will match the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate.		
	d. The date of testing and packaging.		
	e. The expiration date based on stability testing.		
	f. The quantity of cannabidiol oil or THC-A oil contained in the batch.		
	g. A terpenes profile and a list of all active ingredients, including: i. tetrahydrocannabinol (THC). ii. tetrahydrocannabinol acid (THCA). iii. cannabidiol (CBD). iv. cannabidiolic acid (CBDA).		
	h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis.		
	Laboratory Requirements & Testing		**18 VAC 110-60-300**
	No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabidiol oil or THC-A oil unless such laboratory:		
	1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and		
	2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.		

		Result	Notes
	After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board .		
	From the time that a batch of cannabidiol oil or THC-A oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.		
	Under no circumstances shall a pharmaceutical processor sell a cannabidiol oil or THC-A oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.		
	The processor shall require the laboratory to immediately return or properly dispose of any products and materials upon the completion of any testing, use, or research.		
	If a sample of cannabidiol oil or THC-A oil product] does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.		
	1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.		
	2. For purposes of the mycotoxin test, a sample of cannabidiol oil or THC-A oi product shall be deemed to have passed if it meets the following standards:		
	Test Specification / Aflatoxin B1: <20 ug/kg of Substance Aflatoxin B2: <20 ug/kg of Substance Aflatoxin G1: <20 ug/kg of Substance Aflatoxin G2: <20 ug/kg of Substance Ochratoxin A: <20 ug/kg of Substance		
	3. For purposes of the heavy metal test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:		
	Metal / Limits - parts per million (ppm) Arsenic: <10 ppm Cadmium: <4.1 ppm Lead: <10 ppm Mercury: <2 ppm		
	For purposes of the pesticide chemical residue test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.		

		Result	Notes
	For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for: a. Tetrahydrocannabinol (THC); b. Tetrahydrocannabinol acid (THC-A); c. Cannabidiols (CBD); and d. Cannabidiolic acid (CBDA).		
	For the purposes of the residual solvent test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.		
	If a sample of cannabidiol oil or THC-A oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate, packaging, and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.		
	The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.		
	Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians and registered practitioners who have certified qualifying patients.		

Dispensing			
		Result	**Notes**
	Dispensing of CBD or THC-A Oil		**§54.1-3442.7**
	A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil **only in person** to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) such patient's registered agent, or (iii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3.		
	Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall make and maintain for **two years** a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, parent, or legal guardian.		
	Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, registered agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, parent, or legal guardian.		
	A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.		
	No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. *18VAC110-60-10 "90-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.*		
	The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and shall establish a stability testing schedule of THC-A oil		
	18 VAC 110-60-10: "Ninety-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients, which cannot exceed 60 fluid ounces.		
	General Provisions		**18 VAC 110-60-210**
	A pharmaceutical processor shall sell cannabidiol oil or THC-A oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.		
	Only a pharmacist may dispense cannabidiol oil or THC-A oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabidiol oil or THC-A oil.		
	Dispensing of CBD or THC-A Oil		**18 VAC 110-60-310**
	A pharmacist, in good faith, may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification.		

		Result	Notes
	1. Prior to the **initial** dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian.		
	2. The pharmacist or pharmacy technician shall verify in the prescription monitoring program or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.		

		Result	Notes
	3. The pharmacist or pharmacy technician shall make and maintain for **three** years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.		
	4. Prior to any **subsequent** dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, or legal guardian and shall maintain **record** of such viewing in accordance with policies and procedures of the processor.		
	A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian shall receive more than a 90-day supply of cannabidiol oil or THC-A oil in a 90-day period from any pharmaceutical processor.		
	A dispensing record shall be maintained for **three** years from the date of dispensing.		
	The cannabidiol oil or THC-A oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).		
	No person except a pharmacist, or a pharmacy technician operating under the direct supervision of a pharmacist, shall alter, deface, or remove any label so affixed.		
	A pharmacist shall be responsible for verifying the accuracy of the dispensed oil in all respects prior to dispensing and shall document that each verification has been performed.		
	A pharmacist shall document a registered patient's self-assessment of the effects of cannabidiol oil or THC-A oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof.		
	A pharmaceutical processor shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.		
	A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, or legal guardian if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian may have negative health or safety consequences for the registered patient or the public.		
	Dispensing of CBD or THC-A Oil		**54.1-3408.3**
	"Cannabidiol oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law. *Review CBD oil on hand and records of dispensing.*		
	Cannabidiol oil from processed plant extract contains:		
	At least 15% cannabidiol (CBD).		
	No more than 5% tetrahydrocannabinoil (THC).		
	Cannabidiol oil from dilution of resin contains:		
	At least 5mg of cannabidiol per dose.		
	Not more than 5% tetrahydrocannabinol (THC).		
	Dispensed dose does not exceed 10mg of tetrahydrocannabinol.		

		Result	Notes
	"THC-A oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per dose but not more than five percent tetrahydrocannabinol.		
	THC oil from processed plant extract contains:		
	At least 15% tetrahydrocannabinol acid (THC-A).		
	No more than 5% tetrahydrocannabinoil (THC).		
	Cannabidiol oil from dilution of resin contains:		
	At least 5mg of tetrahydrocannabinol acid per dose.		
	Not more than 5% tetrahydrocannabinol (THC).		
	Dispensed dose does not exceed 10mg of tetrahydrocannabinol.		
	Labeling of Dispensed CBD or THC-A Oil		**18 VAC 110-60-310**
	The pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:		
	1. A serial number assigned to the dispensing of the oil.		
	2. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285 and its strength..		
	3. The serial number as assigned to the oil during production.		
	4. The date of dispensing the cannabidiol oil or THC-A oil.		
	5. The quantity of cannabidiol oil or THC-A oil contained therein.		
	6. A terpenes profile and a list of all active ingredients, including: a. Tetrahydrocannabinol (THC). b. Tetrahydrocannabinol acid (THC-A). c. Cannabidiol (CBD). d. Cannabidiolic acid (CBDA)		
	7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and chemical residue analysis.		
	8. The name and registration number of the registered patient.		
	9. The name and registration number of the certifying practitioner.		
	10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner.		
	11. The name or initials of the dispensing pharmacist.		
	12. Name and address, and telephone number of the pharmaceutical processor.		
	13. Any necessary cautionary statement.		
	14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.		
	A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.		

		Result	Notes
Quality Assurance Program			
	Dispensing Error Review, Reporting, Quality Assurance Program		**18 VAC 110-60-320**
	A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors.		
	A pharmaceutical processor shall distribute the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor.		
	Such policies and procedures shall include:		
	1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient.		
	2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.		
	A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:		
	1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program.		
	2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty.		
	3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered.		
	4. Create a record of every quality assurance review. This record shall contain at least the following:		
	a. The date or of the quality assurance review and the names and titles of the persons performing the review.		
	b. The pertinent data and other information relating to the dispensing error reviewed.		
	c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient.		
	d. The findings and determinations generated by the quality assurance review.		
	e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes, if any.		
	A pharmaceutical processor shall maintain for **three** years a copy of the pharmaceutical processor's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.		

		Result	Notes
	Disposal		
	Disposal of CBD or THC-A Oil		**18 VAC 110-60-330**
	To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabidiol oil or THC-A oil nonrecoverable.		
	The destruction shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor.		
	The persons disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating: 1. The date and time of disposal. 2. The manner of disposal. 3. The name and quantity of cannabidiol oil or THC-A oil disposed of. 4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil.		
	The record of disposal shall be maintained at the pharmaceutical processor for **three** years from the date of disposal.		

Good Manufacturing Practices			
Title 21: Food & Drugs PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS			
		Result	Notes
	Subpart B—Personnel		
111.8	**Written Procedures**		
	You must establish and follow written procedures for fulfilling the requirements of this subpart.		
111.10	**Preventing microbial contamination**		
	(a) *Preventing microbial contamination.* You must take measures to exclude from any operations any person who might be a source of microbial contamination, due to a health condition, where such contamination may occur, of any material, including components, dietary supplements, and contact surfaces used in the manufacture, packaging, labeling, or holding of a dietary supplement. Such measures include the following: (1) Excluding from working in any operations that may result in contamination any person who, by medical examination, the person's acknowledgement, or supervisory observation, is shown to have, or appears to have, an illness, infection, open lesion, or any other abnormal source of microbial contamination, that could result in microbial contamination of components, dietary supplements, or contact surfaces, until the health condition no longer exists; and (2) Instructing your employees to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in paragraph (a)(1) of this section that could result in microbial contamination of any components, dietary supplements, or any contact surface. (b) *Hygienic practices.* 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. These hygienic practices include the following: (1) Wearing outer garments in a manner that protects against the contamination of components, dietary supplements, or any contact surface; (2) Maintaining adequate personal cleanliness; (3) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with microorganisms) in an adequate hand-washing facility: (i) Before starting work; and (ii) At any time when the hands may have become soiled or contaminated;		
	(4) Removing all unsecured jewelry and other objects that might fall into components, dietary supplements, equipment, or packaging, and removing hand jewelry that cannot be adequately sanitized during periods in which components or dietary supplements are manipulated by hand. If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against contamination of components, dietary supplements, or contact surfaces; (5) Maintaining gloves used in handling components or dietary supplements in an intact, clean, and sanitary condition. The gloves must be of an impermeable material; (6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints; (7) Not storing clothing or other personal belongings in areas where components, dietary supplements, or any contact surfaces are exposed or where contact surfaces are washed;		

	(8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, dietary supplements, or any contact surfaces are exposed, or where contact surfaces are washed; and		
	(9) Taking any other precautions necessary to protect against the contamination of components, dietary supplements, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.		
111.12	**Personnel qualification requirements**		
	(a) You must have qualified employees who manufacture, package, label, or hold dietary supplements. (b) You must identify who is responsible for your quality control operations. Each person who is identified to perform quality control operations must be qualified to do so and have distinct and separate responsibilities related to performing such operations from those responsibilities that the person otherwise has when not performing such operations. (c) Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions.		
111.13	**Supervisor Requirements**		
	(a) You must assign qualified personnel to supervise the manufacturing, packaging, labeling, or holding of dietary supplements. (b) Each supervisor whom you use must be qualified by education, training, or experience to		
111.14	**Records**		
	(a) You must make and keep records required under this subpart B in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for fulfilling the requirements of this subpart B; and (2) Documentation of training, including the date of the training, the type of training, and the person(s) trained.		
	Subpart C—Physical Plant and Grounds		
111.15	**Sanitation Requirements - Physical Plant & Grounds**		
	(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: (1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding; (2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, dietary supplements, or contact surfaces are exposed; (3) Adequately draining areas that may contribute to the contamination of components, dietary supplements, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests; (4) 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; and (5) If your plant grounds are bordered by grounds not under your control, and if those other 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.		
	(b) *Physical plant facilities* (1) You must maintain your physical plant in a clean and sanitary condition; and (2) You must maintain your physical plant in repair sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated.		

	(c) *Cleaning compounds, sanitizing agents, pesticides, and other toxic materials.* (1) You must use cleaning compounds and sanitizing agents that are free from microorganisms of public health significance and that are safe and adequate under the conditions of use. (2) You must not use or hold toxic materials in a physical plant in which components, dietary supplements, or contact surfaces are manufactured or exposed, unless those materials are necessary as follows: (i) To maintain clean and sanitary conditions; (ii) For use in laboratory testing procedures; (iii) For maintaining or operating the physical plant or equipment; or (iv) For use in the plant's operations. (3) You must identify and hold cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials in a manner that protects against contamination of components, dietary supplements, or contact surfaces.		
	(d) *Pest control* (1) You must not allow animals or pests in any area of your physical plant. Guard or guide dogs are allowed in some areas of your physical plant if the presence of the dogs will not result in contamination of components, dietary supplements, or contact surfaces; (2) You must take effective measures to exclude pests from the physical plant and to protect against contamination of components, dietary supplements, and contact surfaces on the premises by pests; and (3) You must not use insecticides, fumigants, fungicides, or rodenticides, unless you take precautions to protect against the contamination of components, dietary supplements, or contact surfaces.		
	(e) *Water supply* (1) You must provide water that is safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the dietary supplement. (2) 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.		
	(f) *Plumbing.* The plumbing in your physical plant must be of an adequate size and design and be adequately installed and maintained to: (1) Carry sufficient amounts of water to required locations throughout the physical plant; (2) Properly convey sewage and liquid disposable waste from your physical plant; (3) Avoid being a source of contamination to components, dietary supplements, water supplies, or any contact surface, or creating an unsanitary condition; (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and (5) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing dietary supplements, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities.		
	(g) *Sewage disposal.* You must dispose of sewage into an adequate sewage system or through other adequate means.		
	(h) *Bathrooms.* You must provide your employees with adequate, readily accessible bathrooms. The bathrooms must be kept clean and must not be a potential source of contamination to components, dietary supplements, or contact surfaces.		
	(i) *Hand-washing facilities.* You must provide hand-washing facilities that are designed to ensure that an employee's hands are not a source of contamination of components, dietary supplements, or any contact surface, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.		

	(j) *Trash disposal.* You must convey, store, and dispose of trash to: (1) Minimize the development of odors; (2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests; (3) Protect against contamination of components, dietary supplements, any contact surface, water supplies, and grounds surrounding your physical plant; and (4) Control hazardous waste to prevent contamination of components, dietary supplements, and contact surfaces.		
	(k) *Sanitation supervisors.* You must assign one or more employees to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.		
111.16	**Written Procedures**		
	You must establish and follow written procedures for cleaning the physical plant and for pest control.		
111.20	**Design & Construction Requirements**		
	Any physical plant you use in the manufacture, packaging, labeling, or holding of dietary supplements must:		
	(a) Be suitable in size, construction, and design to facilitate maintenance, cleaning, and sanitizing operations;		
	(b) Have adequate space for the orderly placement of equipment and holding of materials as is necessary for maintenance, cleaning, and sanitizing operations and to prevent contamination and mixups of components and dietary supplements during manufacturing, packaging, labeling, or holding;		
	(c) Permit the use of proper precautions to reduce the potential for mixups or contamination of components, dietary supplements, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. Your physical plant must have, and you must use, separate or defined areas of adequate size or other control systems, such as computerized inventory controls or automated systems of separation, to prevent contamination and mixups of components and dietary supplements during the following operations: (1) Receiving, identifying, holding, and withholding from use, components, dietary supplements, packaging, and labels that will be used in or during the manufacturing, packaging, labeling, or holding of dietary supplements; (2) Separating, as necessary, components, dietary supplements, packaging, and labels that are to be used in manufacturing from components, dietary supplements, packaging, or labels that are awaiting material review and disposition decision, reprocessing, or are awaiting disposal after rejection; (3) Separating the manufacturing, packaging, labeling, and holding of different product types including different types of dietary supplements and other foods, cosmetics, and pharmaceutical products; (4) Performing laboratory analyses and holding laboratory supplies and samples; (5) Cleaning and sanitizing contact surfaces; (6) Packaging and label operations; and (7) Holding components or dietary supplements.		

	(d) Be designed and constructed in a manner that prevents contamination of components, dietary supplements, or contact surfaces. (1) The design and construction must include: (i) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair; (ii) Fixtures, ducts, and pipes that do not contaminate components, dietary supplements, or contact surfaces by dripping or other leakage, or condensate; (iii) Adequate ventilation or environmental control equipment such as airflow systems, including filters, fans, and other air-blowing equipment, that minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate components, dietary supplements, or contact surfaces; (iv) Equipment that controls temperature and humidity, when such equipment is necessary to ensure the quality of the dietary supplement; and (v) Aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, dietary supplements, or contact surfaces with clothing or personal contact. (2) When fans and other air-blowing equipment are used, such fans and equipment must be located and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, dietary supplements, or contact surfaces;		
	(e) Provide adequate light in: (1) All areas where components or dietary supplements are examined, processed, or held; (2) All areas where contact surfaces are cleaned; and (3) Hand-washing areas, dressing and locker rooms, and bathrooms.		
	(f) Use safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components or dietary supplements in any step of preparation, unless your physical plant is otherwise constructed in a manner that will protect against contamination of components or dietary supplements in case of breakage of glass or glass-like materials.		
	(g) Provide effective protection against contamination of components and dietary supplements in bulk fermentation vessels, by, for example: (1) Use of protective coverings; (2) Placement in areas where you can eliminate harborages for pests over and around the vessels; (3) Placement in areas where you can check regularly for pests, pest infestation, filth or any other extraneous materials; and (4) Use of skimming equipment. (h) Use adequate screening or other protection against pests, where necessary.		
111.23	**Records**		
	(a) You must make and keep records required under this subpart C in accordance with subpart P of this part. (b) You must make and keep records of the written procedures for cleaning the physical plant and for pest control. (c) You must make and keep records that show that water, when used in a manner such that the water may become a component of the dietary supplement, meets the requirements of §111.15(e)(2).		

	Subpart D—Equipment and Utensils		
111.25	**Written Procedures**		
	You must establish and follow written procedures for fulfilling the requirements of this subpart D, including written procedures for: (a) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement; (b) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and (c) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements.		
111.27	**Equipment & Utensils**		
	(a) You must use equipment and utensils that are of appropriate design, construction, and workmanship to enable them to be suitable for their intended use and to be adequately cleaned and properly maintained. (1) Equipment and utensils include the following: (i) Equipment used to hold or convey; (ii) Equipment used to measure; (iii) Equipment using compressed air or gas; (iv) Equipment used to carry out processes in closed pipes and vessels; and (v) Equipment used in automated, mechanical, or electronic systems.		
	(2) You must use equipment and utensils of appropriate design and construction so that use will not result in the contamination of components or dietary supplements with: (i) Lubricants; (ii) Fuel; (iii) Coolants; (iv) Metal or glass fragments; (v) Filth or any other extraneous material; (vi) Contaminated water; or (vii) Any other contaminants.		
	(3) All equipment and utensils you use must be: (i) Installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces; (ii) Corrosion-resistant if the equipment or utensils contact components or dietary supplements; (iii) Made of nontoxic materials; (iv) Designed and constructed to withstand the environment in which they are used, the action of components or dietary supplements, and, if applicable, cleaning compounds and sanitizing agents; and (v) Maintained to protect components and dietary supplements from being contaminated by any source.		
	(4) Equipment and utensils you use must have seams that are smoothly bonded or maintained to minimize accumulation of dirt, filth, organic material, particles of components or dietary supplements, or any other extraneous materials or contaminants.		
	(5) Each freezer, refrigerator, and other cold storage compartment you use to hold components or dietary supplements: (i) Must be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the temperature accurately within the compartment; and (ii) Must have an automated device for regulating temperature or an automated alarm system to indicate a significant temperature change in a manual operation.		

	(6) Instruments or controls used in the manufacturing, packaging, labeling, or holding of a dietary supplement, and instruments or controls that you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), water activity, or other conditions, to control or prevent the growth of microorganisms or other contamination must be: (i) Accurate and precise; (ii) Adequately maintained; and (iii) Adequate in number for their designated uses.		
	(7) Compressed air or other gases you introduce mechanically into or onto a component, dietary supplement, or contact surface or that you use to clean any contact surface must be treated in such a way that the component, dietary supplement, or contact surface is not contaminated.		
	(b) You must calibrate instruments and controls you use in manufacturing or testing a component or dietary supplement. You must calibrate: (1) Before first use; and (2) At the frequency specified in writing by the manufacturer of the instrument and control; or (3) At routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument and control.		
	(c) You must repair or replace instruments or controls that cannot be adjusted to agree with the reference standard.		
	(d) You must maintain, clean, and sanitize, as necessary, all equipment, utensils, and any other contact surfaces used to manufacture, package, label, or hold components or dietary supplements. (1) Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing. (2) You must ensure that all contact surfaces, used for manufacturing or holding low-moisture components or dietary supplements, are in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use. (3) If you use wet processing during manufacturing, you must clean and sanitize all contact surfaces, as necessary, to protect against the introduction of microorganisms into components or dietary supplements. When cleaning and sanitizing is necessary, you must clean and sanitize all contact surfaces before use and after any interruption during which the contact surface may have become contaminated. If you use contact surfaces in a continuous production operation or in consecutive operations involving different batches of the same dietary supplement, you must adequately clean and sanitize the contact surfaces, as necessary. (4) You must clean surfaces that do not come into direct contact with components or dietary supplements as frequently as necessary to protect against contaminating components or dietary supplements. (5) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be: (i) Stored in appropriate containers; and (ii) Handled, dispensed, used, and disposed of in a manner that protects against contamination of components, dietary supplements, or any contact surface. (6) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use; (7) You must store cleaned and sanitized portable equipment and utensils that have contact surfaces in a location and manner that protects them from contamination.		

111.30	**Mechanical & Electronic Equipment**		
	For any automated, mechanical, or electronic equipment that you use to manufacture, package, label, or hold a dietary supplement, you must: (a) Design or select equipment to ensure that dietary supplement specifications are consistently met; (b) Determine the suitability of the equipment by ensuring that your equipment is capable of operating satisfactorily within the operating limits required by the process; (c) Routinely calibrate, inspect, or check the equipment to ensure proper performance. Your quality control personnel must periodically review these calibrations, inspections, or checks; (d) 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 and instituted only by authorized personnel; and (e) 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.		
111.30	**Records**		
	(a) You must make and keep records required under this subpart D in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for fulfilling the requirements of this subpart, including written procedures for: (i) Calibrating instruments and controls that you use in manufacturing or testing a component or dietary supplement; (ii) Calibrating, inspecting, and checking automated, mechanical, and electronic equipment; and (iii) Maintaining, cleaning, and sanitizing, as necessary, all equipment, utensils, and any other contact surfaces that are used to manufacture, package, label, or hold components or dietary supplements; (2) Documentation, in individual equipment logs, of the date of the use, maintenance, cleaning, and sanitizing of equipment, unless such documentation is kept with the batch record; (3) Documentation of any calibration, each time the calibration is performed, for instruments and controls that you use in manufacturing or testing a component or dietary supplement. In your documentation, you must: (i) Identify the instrument or control calibrated; (ii) Provide the date of calibration; (iii) Identify the reference standard used including the certification of accuracy of the known reference standard and a history of recertification of accuracy; (iv) Identify the calibration method used, including appropriate limits for accuracy and precision of instruments and controls when calibrating; (v) Provide the calibration reading or readings found; (vi) Identify the recalibration method used, and reading or readings found, if accuracy or precision or both accuracy and precision limits for instruments and controls were not met; and (vii) Include the initials of the person who performed the calibration and any recalibration. (4) Written records of calibrations, inspections, and checks of automated, mechanical, and electronic equipment;		

	(5) Backup file(s) of current software programs (and of outdated software that is necessary to retrieve records that you are required to keep in accordance with subpart P of this part, when current software is not able to retrieve such records) and of data entered into computer systems that you use to manufacture, package, label, or hold dietary supplements. (i) Your backup file (e.g., a hard copy of data you have entered, diskettes, tapes, microfilm, or compact disks) must be an exact and complete record of the data you entered. (ii) You must keep your backup software programs and data secure from alterations, inadvertent erasures, or loss; and (6) Documentation of the controls that you use to ensure that equipment functions in accordance with its intended use.		
	Subpart E—Production and Process Control System		
111.55	**Requirements to implement a production and process control system**		
	You must implement a system of production and process controls that covers all stages of manufacturing, packaging, labeling, and holding of the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.		
111.60	**Design requirements for the production and process control system**		
	(a) Your production and in-process control system must be designed to ensure that the dietary supplement is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record; and (b) The production and in-process control system must include all requirements of subparts E through L of this part and must be reviewed and approved by quality control personnel.		
111.65	**Requirements for quality control operations**		
	You must implement quality control operations in your manufacturing, packaging, labeling, and holding operations for producing the dietary supplement to ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record.		
111.70	**Specifications**		
	(a) You must establish a specification for any 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. (b) For each component that you use in the manufacture of a dietary supplement, you must establish component specifications as follows: (1) You must establish an identity specification; (2) You must establish component specifications that are necessary to ensure that specifications for the purity, strength and composition of dietary supplements manufactured using the components are met; and (3) You must establish limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement to ensure the quality of the dietary supplement.		

	(c) For the in-process production: (1) You must establish in-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the dietary supplements and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; (2) You must provide adequate documentation of your basis for why meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for the identity, purity, strength, and composition of the dietary supplements and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and (3) Quality control personnel must review and approve the documentation that you provide under paragraph (c)(2) of this section. (d) You must establish specifications for dietary supplement labels (label specifications) and for packaging that may come in contact with dietary supplements (packaging specifications). Packaging that may come into contact with dietary supplements must be safe and suitable for its intended use and must not be reactive or absorptive or otherwise affect the safety or quality of the dietary supplement. (e) For each dietary supplement that you manufacture you must establish product specifications for the identity, purity, strength, and composition of the finished batch of the dietary supplement, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the dietary supplement to ensure the quality of the dietary supplement. (f) If you receive a product from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must establish specifications to provide sufficient assurance that the product you receive is adequately identified and is consistent with your purchase order. (g) You must establish specifications for the packaging and labeling of the finished packaged and labeled dietary supplements, including specifications that ensure that you used the specified packaging and that you applied the specified label.		
111.73	**Responsibility for determining whether established specifications**		
	You must determine whether the specifications you establish under §111.70 are met.		
111.75	**Responsibility for determining whether established specifications**		
	(a) Before you use a component, you must: (1) (i) Conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient, unless you petition the agency under paragraph (a)(1)(ii) of this section and the agency exempts you from such testing; (ii) You may submit a petition, under 21 CFR 10.30, to request an exemption from the testing requirements in paragraph (a)(1)(i) of this section. The petition must set forth the scientific rationale, and must be accompanied by the supporting data and information, for proposed alternative testing that will demonstrate that there is no material diminution of assurance, compared to the assurance provided by 100 percent identity testing, of the identity of the dietary ingredient before use when the dietary ingredient is obtained from one or more suppliers identified in the petition. If FDA grants the petition, you must conduct the tests and examinations for the dietary ingredient, otherwise required under §111.75(a)(1)(i), under the terms specified by FDA when the petition is granted; and		

	(2) Confirm the identity of other components and determine whether other applicable component specifications established in accordance with §111.70(b) are met. To do so, you must either: (i) Conduct appropriate tests or examinations; or (ii) Rely on a certificate of analysis from the supplier of the component that you receive, provided that: (A) You first qualify the supplier by establishing the reliability of the supplier's certificate of analysis through confirmation of the results of the supplier's tests or examinations; (B) The certificate of analysis includes a description of the test or examination method(s) used, limits of the test or examinations, and actual results of the tests or examinations; (C) You maintain documentation of how you qualified the supplier; (D) You periodically re-confirm the supplier's certificate of analysis; and (E) Your quality control personnel review and approve the documentation setting forth the basis for qualification (and re-qualification) of any supplier.		
	(b) You must monitor the in-process points, steps, or stages where control is necessary to ensure the quality of the finished batch of dietary supplement to: (1) Determine whether the in-process specifications are met; and (2) Detect any deviation or unanticipated occurrence that may result in a failure to meet specifications.		
	(c) For a subset of finished dietary supplement batches that you identify through a sound statistical sampling plan (or for every finished batch), you must verify that your finished batch of the dietary supplement meets product specifications for identity, purity, strength, composition, and for limits on those types of contamination that may adulterate or that may lead to adulteration of the finished batch of the dietary supplement. To do so: (1) You must select one or more established specifications for identity, purity, strength, composition, and the limits on those types of contamination that may adulterate or that may lead to adulteration of the dietary supplement that, if tested or examined on the finished batches of the dietary supplement, would verify that the production and process control system is producing a dietary supplement that meets all product specifications (or only those product specifications not otherwise exempted from this provision by quality control personnel under paragraph (d) of this section); (2) You must conduct appropriate tests or examinations to determine compliance with the specifications selected in paragraph (c)(1) of this section; (3) You must provide adequate documentation of your basis for determining that compliance with the specification(s) selected under paragraph (c)(1) of this section, through the use of appropriate tests or examinations conducted under paragraph (c)(2) of this section, will ensure that your finished batch of the dietary supplement meets all product specifications for identity, purity, strength, and composition, and the limits on those types of contamination that may adulterate, or that may lead to the adulteration of, the dietary supplement; and (4) Your quality control personnel must review and approve the documentation that you provide under paragraph (c)(3) of this section.		

	(d) (1) You may exempt one or more product specifications from verification requirements in paragraph (c)(1) of this section if you determine and document that the specifications you select under paragraph (c)(1) of this section for determination of compliance with specifications are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage. In such a case, you must document why, for example, any component and in-process testing, examination, or monitoring, and any other information, will ensure that such exempted product specification is met without verification through periodic testing of the finished batch; and (2) Your quality control personnel must review and approve the documentation that you provide under paragraph (d)(1) of this section.		
	(e) Before you package or label a product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier), you must visually examine the product and have documentation to determine whether the specifications that you established under §111.70 (f) are met.		
	(f) (1) Before you use packaging, you must, at a minimum, conduct a visual identification of the containers and closures and review the supplier's invoice, guarantee, or certification to determine whether the packaging specifications are met; and (2) Before you use labels, you must, at a minimum, conduct a visual examination of the label and review the supplier's invoice, guarantee, or certification to determine whether label specifications are met.		
	(g) You must, at a minimum, conduct a visual examination of the packaging and labeling of the finished packaged and labeled dietary supplements to determine whether you used the specified packaging and applied the specified label.		
	(h) (1) You must ensure that the tests and examinations that you use to determine whether the specifications are met are appropriate, scientifically valid methods. (2) The tests and examinations that you use must include at least one of the following: (i) Gross organoleptic analysis; (ii) Macroscopic analysis; (iii) Microscopic analysis; (iv) Chemical analysis; or (v) Other scientifically valid methods. (i) You must establish corrective action plans for use when an established specification is not met.		
111.77	**What you must do if established specifications are not met**		
	(a) For specifications established under §111.70(a), (b)(2), (b)(3), (c), (d), (e), and (g) that you do not meet, quality control personnel, in accordance with the requirements in subpart F of this part, must reject the component, dietary supplement, package or label unless such personnel approve a treatment, an in-process adjustment, or reprocessing that will ensure the quality of the finished dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. No finished batch of dietary supplements may be released for distribution unless it complies with §111.123(b). (b) For specifications established under §111.70(b)(1) that you do not meet, quality control personnel must reject the component and the component must not be used in manufacturing the dietary supplement. (c) For specifications established under §111.70(f) that you do not meet, quality control personnel must reject the product and the product may not be packaged or labeled for distribution as a dietary supplement.		

111.80	**Sample Collection**		
	The representative samples that you must collect include: (a) Representative samples of each unique lot of components, packaging, and labels that you use to determine whether the components, packaging, and labels meet specifications established in accordance with §111.70(b) and (d), and as applicable, §111.70(a) (and, when you receive components, packaging, or labels from a supplier, representative samples of each unique shipment, and of each unique lot within each unique shipment); (b) Representative samples of in-process materials for each manufactured batch at points, steps, or stages, in the manufacturing process as specified in the master manufacturing record where control is necessary to ensure the identity, purity, strength, and composition of dietary supplements to determine whether the in-process materials meet specifications established in accordance with §111.70(c), and as applicable, §111.70(a); (c) Representative samples of a subset of finished batches of each dietary supplement that you manufacture, which you identify through a sound statistical sampling plan (or otherwise every finished batch), before releasing for distribution to verify that the finished batch of dietary supplement meets product specifications established in accordance with §111.70(e), and as applicable, §111.70(a); (d) Representative samples of each unique shipment, and of each unique lot within each unique shipment, of product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) to determine whether the received product meets specifications established in accordance with §111.70(f), and as applicable, §111.70(a); and (e) Representative samples of each lot of packaged and labeled dietary supplements to determine whether the packaging and labeling of the finished packaged and labeled dietary supplements meet specifications established in accordance with §111.70(g), and as applicable, §111.70(a).		
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: (1) 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; (2) Be identified with the batch, lot, or control number; (3) 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; and (4) Consist of at least twice the quantity necessary for all tests or examinations to determine whether or not the dietary supplement meets product specifications.		
111.87	**Material Review & Disposition Decision**		
	Quality control personnel must conduct all required material reviews and make all required disposition decisions.		

111.90	**Requirements that apply to treatments, in-process adjustments, and reprocessing when there is a deviation or unanticipated occurrence or when a specification established in accordance with §111.70 is not met**		
	(a) You must not reprocess a rejected dietary supplement or treat or provide an in-process adjustment to a component, packaging, or label to make it suitable for use in the manufacture of a dietary supplement unless: (1) Quality control personnel conduct a material review and make a disposition decision to approve the reprocessing, treatment, or in-process adjustment; and (2) The reprocessing, treatment, or in-process adjustment is permitted by §111.77; (b) You must not reprocess any dietary supplement or treat or provide an in-process adjustment to a component to make it suitable for use in the manufacture of a dietary supplement, unless: (1) Quality control personnel conduct a material review and make a disposition decision that is based on a scientifically valid reason and approves the reprocessing, treatment, or in-process adjustment; and (2) The reprocessing, treatment or in-process adjustment is permitted by §111.77; (c) Any batch of dietary supplement that is reprocessed, that contains components that you have treated, or to which you have made in-process adjustments to make them suitable for use in the manufacture of the dietary supplement must be approved by quality control personnel and comply with §111.123(b) before releasing for distribution.		
111.95	**Records**		
	(a) You must make and keep records required under this subpart E in accordance with subpart P of this part. (b) Under this subpart E, you must make and keep the following records: (1) The specifications established; (2) Documentation of your qualification of a supplier for the purpose of relying on the supplier's certificate of analysis; (3) Documentation for why meeting in-process specifications, in combination with meeting component specifications, helps ensure that the dietary supplement meets the specifications for identity, purity, strength, and composition; and for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the dietary supplement; and (4) Documentation for why the results of appropriate tests or examinations for the product specifications selected under §111.75(c)(1) ensure that the dietary supplement meets all product specifications; (5) Documentation for why any component and in-process testing, examination, or monitoring, and any other information, will ensure that a product specification that is exempted under §111.75(d) is met without verification through periodic testing of the finished batch, including documentation that the selected specifications tested or examined under §111.75 (c)(1) are not able to verify that the production and process control system is producing a dietary supplement that meets the exempted product specification and there is no scientifically valid method for testing or examining such exempted product specification at the finished batch stage. (6) Documentation of FDA's response to a petition submitted under §111.75(a)(1)(ii) providing for an exemption from the provisions of §111.75(a)(1)(i).		

	Subpart F— Quality Control		
111.103	**Written Procedures**		
	You must establish and follow written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing.		
111.105	**Quality Control Personnel** Quality control personnel must ensure that your manufacturing, packaging, labeling, and holding operations ensure the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. To do so, quality control personnel must perform operations that include: (a) Approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a dietary supplement; (b) Reviewing and approving the documentation setting forth the basis for qualification of any supplier; (c) Reviewing and approving the documentation setting forth the basis for why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition of the dietary supplement are met; (d) Reviewing and approving the documentation setting forth the basis for why the results of appropriate tests or examinations for each product specification selected under §111.75(c)(1) will ensure that the finished batch of the dietary supplement meets product specifications; (e) Reviewing and approving the basis and the documentation for why any product specification is exempted from the verification requirements in §111.75(c)(1), and for why any component and in-process testing, examination, or monitoring, or other methods will ensure that such exempted product specification is met without verification through periodic testing of the finished batch; (f) Ensuring that required representative samples are collected; (g) Ensuring that required reserve samples are collected and held; (h) Determining whether all specifications established under §111.70(a) are met; and (i) Performing other operations required under this subpart.		
111.110	**Quality control operations for laboratory operations**		
	Quality control operations for laboratory operations associated with the production and process control system must include: (a) Reviewing and approving all laboratory control processes associated with the production and process control system; (b) Ensuring that all tests and examinations required under §111.75 are conducted; and (c) Reviewing and approving the results of all tests and examinations required under §111.75.		
111.113	**Quality control operations for a material review and disposition decision**		
	(a) Quality control personnel must conduct a material review and make a disposition decision if: (1) A specification established in accordance with §111.70 is not met; (2) A batch deviates from the master manufacturing record, including when any step established in the master manufacturing record is not completed and including any deviation from specifications; (3) There is any unanticipated occurrence during the manufacturing operations that adulterates or may lead to adulteration of the component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record;		

	(4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch or batches of a dietary supplement; or (5) A dietary supplement is returned. (b) (1) When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to adulteration of a component, dietary supplement, or packaging, or could lead to the use of a label not specified in the master manufacturing record, quality control personnel must reject the component, dietary supplement, packaging, or label unless it approves a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence. (2) When a specification established in accordance with §111.70 is not met, quality control personnel must reject the component, dietary supplement, package or label, unless quality control personnel approve a treatment, an in-process adjustment, or reprocessing, as permitted in §111.77. (c) The person who conducts a material review and makes the disposition decision must, at the time of performance, document that material review and disposition decision.		
111.117	**Quality control operations for equipment, instruments, and controls**		
	Quality control operations for equipment, instruments, and controls must include: (a) Reviewing and approving all processes for calibrating instruments and controls; (b) Periodically reviewing all records for calibration of instruments and controls; (c) Periodically reviewing all records for calibrations, inspections, and checks of automated, mechanical, or electronic equipment; and (d) Reviewing and approving controls to ensure that automated, mechanical, or electronic equipment functions in accordance with its intended use.		
111.120	**Quality control operations for components, packaging, and labels before use in the manufacture of a dietary supplement**		
	Quality control operations for components, packaging, and labels before use in the manufacture of a dietary supplement must include: (a) Reviewing all receiving records for components, packaging, and labels; (b) Determining whether all components, packaging, and labels conform to specifications established under §111.70 (b) and (d); (c) Conducting any required material review and making any required disposition decision; (d) Approving or rejecting any treatment and in-process adjustments of components, packaging, or labels to make them suitable for use in the manufacture of a dietary supplement; and (e) Approving, and releasing from quarantine, all components, packaging, and labels before they are used.		
111.123	**Quality control operations for the master manufacturing record, the batch production record, and manufacturing operations**		
	(a) Quality control operations for the master manufacturing record, the batch production record, and manufacturing operations must include: (1) Reviewing and approving all master manufacturing records and all modifications to the master manufacturing records; (2) Reviewing and approving all batch production-related records; (3) Reviewing all monitoring required under subpart E; (4) Conducting any required material review and making any required disposition decision; (5) Approving or rejecting any reprocessing; (6) Determining whether all in-process specifications established in accordance with §111.70(c) are met; (7) Determining whether each finished batch conforms to product specifications established in accordance with §111.70(e); and (8) Approving and releasing, or rejecting, each finished batch for distribution, including any reprocessed finished batch.		

	(b) Quality control personnel must not approve and release for distribution: (1) Any batch of dietary supplement for which any component in the batch does not meet its identity specification; (2) Any batch of dietary supplement, including any reprocessed batch, that does not meet all product specifications established in accordance with §111.70(e); (3) Any batch of dietary supplement, including any reprocessed batch, that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under section 402(a)(1), (a)(2), (a)(3), and (a)(4) of the act; and (4) Any product received from a supplier for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for which sufficient assurance is not provided to adequately identify the product and to determine that the product is consistent with your purchase order.		
111.127	**Quality control operations for packaging and labeling operations**		
	Quality control operations for packaging and labeling operations must include: (a) Reviewing the results of any visual examination and documentation to ensure that specifications established under §111.70(f) are met for all products that you receive for packaging and labeling as a dietary supplement (and for distribution rather than for return to the supplier); (b) Approving, and releasing from quarantine, all products that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) before they are used for packaging or labeling; (c) Reviewing and approving all records for packaging and label operations; (d) Determining whether the finished packaged and labeled dietary supplement conforms to specifications established in accordance with §111.70(g); (e) Conducting any required material review and making any required disposition decision; (f) Approving or rejecting any repackaging of a packaged dietary supplement; (g) Approving or rejecting any relabeling of a packaged and labeled dietary supplement; and (h) Approving for release, or rejecting, any packaged and labeled dietary supplement (including a repackaged or relabeled dietary supplement) for distribution.		
111.130	**Quality control operations for 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: (1) Determining whether tests or examination are necessary to determine compliance with product specifications established in accordance with §111.70(e); and (2) Reviewing the results of any tests or examinations that are conducted to determine compliance with product specifications established in accordance with §111.70(e); (b) Approving or rejecting any salvage and redistribution of any returned dietary supplement; (c) Approving or rejecting any reprocessing of any returned dietary supplement; and (d) Determining whether the reprocessed dietary supplement meets product specifications and either approving for release, or rejecting, any returned dietary supplement that is reprocessed.		
111.135	**Quality control operations for product complaints**		
	Quality control operations for product complaints must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings and follow-up action of any investigation performed.		

111.140	**Records**		
	(a) You must make and keep the records required under this subpart F in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing; (2) Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following: (i) Date that the review, approval, or rejection was performed; and (ii) Signature of the person performing the review, approval, or rejection; and (3) Documentation of any material review and disposition decision and follow-up. Such documentation must be included in the appropriate batch production record and must include: (i) Identification of the specific deviation or the unanticipated occurrence; (ii) Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence; (iii) Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the dietary supplement or a failure to package and label the dietary supplement as specified in the master manufacturing record; (iv) Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence; (v) Explanation of what you did with the component, dietary supplement, packaging, or label; (vi) A scientifically valid reason for any reprocessing of a dietary supplement that is rejected or any treatment or in-process adjustment of a component that is rejected; and (vii) The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provides information relevant to that material review and disposition decision.		
	Subpart G— Requirements for Components, Packaging, and Labels and for Product That You Receive for Packaging or Labeling as a Dietary Supplement		
111.153	**Written Procedures**		
	You must establish and follow written procedures for fulfilling the requirements of this subpart G.		
111.155	**Requirements that apply to components of dietary supplements**		
	(a) You must visually examine each immediate container or grouping of immediate containers in a shipment that you receive for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the components; (b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment you receive to ensure the components are consistent with your purchase order; (c) You must quarantine components before you use them in the manufacture of a dietary supplement until: (1) You collect representative samples of each unique lot of components (and, for components that you receive, of each unique shipment, and of each unique lot within each unique shipment); (2) Quality control personnel review and approve the results of any tests or examinations conducted on components; and		

	(3) Quality control personnel approve the components for use in the manufacture of a dietary supplement, including approval of any treatment (including in-process adjustments) of components to make them suitable for use in the manufacture of a dietary supplement, and releases them from quarantine. (d) (1) You must identify each unique lot within each unique shipment of components that you receive and any lot of components that you produce in a manner that allows you to trace the lot to the supplier, the date received, the name of the component, the status of the component (e.g., quarantined, approved, or rejected); and to the dietary supplement that you manufactured and distributed. (2) You must use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of components that you receive and any lot of components that you produce. (e) You must hold components under conditions that will protect against contamination and deterioration, and avoid mix-ups.		
111.160	**Requirements that apply to packaging and labels received**		
	(a) You must visually examine each immediate container or grouping of immediate containers in a shipment for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the packaging and labels. (b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment to ensure that the packaging or labels are consistent with your purchase order. (c) You must quarantine packaging and labels before you use them in the manufacture of a dietary supplement until: (1) You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of packaging and labels and, at a minimum, conduct a visual identification of the immediate containers and closures; (2) Quality control personnel review and approve the results of any tests or examinations conducted on the packaging and labels; and (3) Quality control personnel approve the packaging and labels for use in the manufacture of a dietary supplement and release them from quarantine. (d) (1) You must identify each unique lot within each unique shipment of packaging and labels in a manner that allows you to trace the lot to the supplier, the date received, the name of the packaging and label, the status of the packaging and label (e.g., quarantined, approved, or rejected); and to the dietary supplement that you distributed; and (2) You must use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of packaging and labels. (e) You must hold packaging and labels under conditions that will protect against contamination and deterioration, and avoid mix-ups.		
111.165	**§111.165 What requirements apply to a product received for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier)?**		
	(a) You must visually examine each immediate container or grouping of immediate containers in a shipment of product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier) for appropriate content label, container damage, or broken seals to determine whether the container condition may have resulted in contamination or deterioration of the received product. (b) You must visually examine the supplier's invoice, guarantee, or certification in a shipment of the received product to ensure that the received product is consistent with your purchase order.		

	(c) You must quarantine the received product until: (1) You collect representative samples of each unique shipment, and of each unique lot within each unique shipment, of received product; (2) Quality control personnel review and approve the documentation to determine whether the received product meets the specifications that you established under §111.70(f); and (3) Quality control personnel approve the received product for packaging or labeling as a dietary supplement and release the received product from quarantine. (d) (1) You must identify each unique lot within each unique shipment of received product in a manner that allows you to trace the lot to the supplier, the date received, the name of the received product, the status of the received product (e.g., quarantined, approved, or rejected), and to the product that you packaged or labeled and distributed as a dietary supplement. (2) You must use this unique identifier whenever you record the disposition of each unique lot within each unique shipment of the received product. (e) You must hold the received product under conditions that will protect against contamination and deterioration, and avoid mix-ups.		
111.170	**Requirements that 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	**Records**		
	(a) You must make and keep records required under this subpart G in accordance with subpart P of this part. (b) 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.		

	Subpart H—Requirements for the Master Manufacturing Record		
111.205	**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: (1) 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; and (2) Establish controls and procedures to ensure that each batch of dietary supplement that you manufacture meets the specifications identified in accordance with paragraph (b)(1) of this section. (c) You must make and keep master manufacturing records in accordance with subpart P of this part.		
111.210	**Master Manufacturing Record Content**		
	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— Batch Production Record		
111.255	**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 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 Record**		
	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 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:		
	(1) The date on which each step of the master manufacturing record was performed; 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 measure 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 components 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 reconciliation 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 location of the actual or representative label specified in the master manufacturing record; and		
	(3) 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:		
	(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 supplements;		
	(2) Approved or rejected any reprocessing or repackaging; and		
	(3) Approved and released, or rejected, the batch for distribution, including any reprocessed batch; and		
	(4) 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.		
	Subpart J—Laboratory Operations		
111.303	**Written Procedures**		
	You must establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met.		
111.310	**Laboratory Requirements**		
	You must use adequate laboratory facilities to perform whatever testing and examinations are necessary to determine whether: (a) Components that you use meet specifications; (b) In-process specifications are met as specified in the master manufacturing record; and (c) Dietary supplements that you manufacture meet specifications.		
111.315	**§111.315 What are the requirements for laboratory control processes?**		
	You must establish and follow laboratory control processes that are reviewed and approved by quality control personnel, including the following: (a) Use of criteria for establishing appropriate specifications; (b) Use of sampling plans for obtaining representative samples, in accordance with subpart E of this part, of: (1) Components, packaging, and labels; (2) In-process materials; (3) Finished batches of dietary supplements; (4) Product that you receive for packaging or labeling as a dietary supplement (and for distribution rather than for return to the supplier); and (5) Packaged and labeled dietary supplements. (c) Use of criteria for selecting appropriate examination and testing methods; (d) Use of criteria for selecting standard reference materials used in performing tests and examinations; and (e) Use of test methods and examinations in accordance with established criteria.		

111.320	**Laboratory methods for testing and examination**		
	(a) You must verify that the laboratory examination and testing methodologies are appropriate for their intended use. (b) You must identify and use an appropriate scientifically valid method for each established specification for which testing or examination is required to determine whether the specification is met.		
111.325	**Records** (a) You must make and keep records required under this subpart J in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for laboratory operations, including written procedures for the tests and examinations that you conduct to determine whether specifications are met; (2) Documentation that laboratory methodology established in accordance with this subpart J is followed. (i) The person who conducts the testing and examination must document, at the time of performance, that laboratory methodology established in accordance with this subpart J is followed. (ii) The documentation for laboratory tests and examinations must include the results of the testing and examination.		
	Subpart K—Production and Process Control System: Requirements for Manufacturing Operations		
111.353	**Written Procedures**		
	You must establish and follow written procedures for manufacturing operations.		
111.355	**Design requirements for manufacturing operations**		
	You must design or select manufacturing processes to ensure that product specifications are consistently met.		
111.360	**Sanitation**		
	You must conduct all manufacturing operations in accordance with adequate sanitation principles.		
111.365	**Precautions to prevent contamination**		
	You must take all the necessary precautions during the manufacture of a dietary supplement to prevent contamination of components or dietary supplements. These precautions include: (a) Performing manufacturing operations under conditions and controls that protect against the potential for growth of microorganisms and the potential for contamination; (b) Washing or cleaning components that contain soil or other contaminants; (c) Using water that, at a minimum, complies with the applicable Federal, State, and local requirements and does not contaminate the dietary supplement when the water may become a component of the finished batch of dietary supplement; (d) Performing chemical, microbiological, or other testing, as necessary to prevent the use of contaminated components; (e) Sterilizing, pasteurizing, freezing, refrigerating, controlling hydrogen-ion concentration (pH), controlling humidity, controlling water activity (a_w), or using any other effective means to remove, destroy, or prevent the growth of microorganisms and prevent decomposition; (f) Holding components and dietary supplements that can support the rapid growth of microorganisms of public health significance in a manner that prevents the components and dietary supplements from becoming adulterated; (g) Identifying and holding any components or dietary supplements, for which a material review and disposition decision is required, in a manner that protects components or dietary supplements that are not under a material review against contamination and mix-ups with those that are under a material review;		

	(h) Performing mechanical manufacturing steps (such as cutting, sorting, inspecting, shredding, drying, grinding, blending, and sifting) by any effective means to protect the dietary supplements against contamination, by, for example: (1) Cleaning and sanitizing contact surfaces; (2) Using temperature controls; and (3) Using time controls. (i) Using effective measures to protect against the inclusion of metal or other foreign material in components or dietary supplements, by, for example: (1) Filters or strainers, (2) Traps, (3) Magnets, or (4) Electronic metal detectors. (j) Segregating and identifying all containers for a specific batch of dietary supplements to identify their contents and, when necessary, the phase of manufacturing; and (k) Identifying all processing lines and major equipment used during manufacturing to indicate their contents, including the name of the dietary supplement and the specific batch or lot number and, when necessary, the phase of manufacturing.		
111.370	**Rejected dietary supplements**		
	You must clearly identify, hold, and control under a quarantine system for appropriate disposition any dietary supplement that is rejected and unsuitable for use in manufacturing, packaging, or labeling operations.		
111.375	**Records**		
	(a) You must make and keep records required under this subpart K in accordance with subpart P of this part. (b) You must make and keep records of the written procedures for manufacturing operations.		
	Subpart L—Packaging and Labeling Operations		
111.403	**Written Procedures**		
	You must establish and follow written procedures for packaging and labeling operations.		
111.410	**Packaging & labeling**		
	(a) You must take necessary actions to determine whether packaging for dietary supplements meets specifications so that the condition of the packaging will ensure the quality of your dietary supplements; (b) You must control the issuance and use of packaging and labels and reconciliation of any issuance and use discrepancies. Label reconciliation is not required for cut or rolled labels if a 100-percent examination for correct labels is performed by appropriate electronic or electromechanical equipment during or after completion of finishing operations; and (c) You must examine, before packaging and labeling operations, packaging and labels for each batch of dietary supplement to determine whether the packaging and labels conform to the master manufacturing record; and (d) You must be able to determine the complete manufacturing history and control of the packaged and labeled dietary supplement through distribution.		

111.415	**Filling, assembling, packaging, labeling, and related operations**		
	You must fill, assemble, package, label, and perform other related operations in a way that ensures the quality of the dietary supplement and that the dietary supplement is packaged and labeled as specified in the master manufacturing record. You must do this using any effective means, including the following: (a) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary supplement packaging, as appropriate; (b) Protecting manufactured dietary supplements from contamination, particularly airborne contamination; (c) Using sanitary handling procedures; (d) Establishing physical or spatial separation of packaging and label operations from operations on other components and dietary supplements to prevent mix-ups; (e) Identifying, by any effective means, filled dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mix-ups; (f) Assigning a batch, lot, or control number to: (1) Each lot of packaged and labeled dietary supplement from a finished batch of dietary supplement; and, (2) Each lot of dietary supplement, from a finished batch of dietary supplement, that you distribute to another person for packaging or labeling. (g) Examining a representative sample of each batch of the packaged and labeled dietary supplement to determine whether the dietary supplement meets specifications established in accordance with §111.70(g); and (h) Suitably disposing of labels and packaging for dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.		
111.420	**Repackaging and relabeling**		
	(a) You may repackage or relabel dietary supplements only after quality control personnel have approved such repackaging or relabeling. (b) You must examine a representative sample of each batch of repackaged or relabeled dietary supplements to determine whether the repackaged or relabeled dietary supplements meet all specifications established in accordance with §111.70(g). (c) Quality control personnel must approve or reject each batch of repackaged or relabeled dietary supplement prior to its release for distribution.		
111.425	**Packaged and labeled dietary supplement that is rejected for distribution**		
	You must clearly identify, hold, and control under a quarantine system for appropriate disposition any packaged and labeled dietary supplement that is rejected for distribution.		
111.430	**Records**		
	(a) You must make and keep records required under this subpart L in accordance with subpart P of this part. (b) You must make and keep records of the written procedures for packaging and labeling operations.		
	Subpart M—Holding and Distributing		
111.453	**Written Procedures**		
	You must establish and follow written procedures for holding and distributing operations.		
111.455	**Holding components, dietary supplements, packaging, and labels** (a) You must hold components and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and dietary supplements are not affected. (b) You must hold packaging and labels under appropriate conditions so that the packaging and labels are not adversely affected. (c) You must hold components, dietary supplements, packaging, and labels under conditions that do not lead to the mix-up, contamination, or deterioration of components, dietary supplements, packaging, and labels.		

111.460	**Holding in-process material**		
	(a) You must identify and hold in-process material under conditions that protect against mix-up, contamination, and deterioration. (b) You must hold in-process material under appropriate conditions of temperature, humidity, and light.		
111.465	**Holding reserve samples of dietary supplements**		
	(a) You must hold reserve samples of dietary supplements in a manner that protects against contamination and deterioration. This includes: (1) 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 (2) 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. (b) 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.		
111.470	**Distributing dietary supplements**		
	You must distribute dietary supplements under conditions that will protect the dietary supplements against contamination and deterioration.		
111.475	**Records**		
	(a) You must make and keep records required under this subpart M in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for holding and distributing operations; and (2) Records of product distribution.		
	Subpart N—Returned Dietary Supplements		
111.503	**Written Procedures**		
	You must establish and follow written procedures to fulfill the requirements of this subpart.		
111.510	**Receipt of returned dietary supplement** You must identify and quarantine returned dietary supplements until quality control personnel conduct a material review and make a disposition decision.		
111.515	**Destruction or disposal of returned dietary supplement** You must destroy, or otherwise suitably dispose of, any returned dietary supplement unless the outcome of a material review and disposition decision is that quality control personnel do the following: (a) Approve the salvage of the returned dietary supplement for redistribution or (b) Approve the returned dietary supplement for reprocessing.		
111.520	**Salvaging of a returned dietary supplement**		
	You may salvage a returned dietary supplement only if quality control personnel conduct a material review and make a disposition decision to allow the salvage.		
111.525	**Returned dietary supplement that quality control personnel approve for reprocessing**		
	(a) You must ensure that any returned dietary supplements that are reprocessed meet all product specifications established in accordance with §111.70(e); and (b) Quality control personnel must approve or reject the release for distribution of any returned dietary supplement that is reprocessed.		
111.530	**Investigation of manufacturing processes and other batches?**		
	If the reason for a dietary supplement being returned implicates other batches, you must conduct an investigation of your manufacturing processes and each of those other batches to determine compliance with specifications.		

111.535	**Records**		
	(a) You must make and keep records required under this subpart N in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for fulfilling the requirements of this subpart N. (2) Any material review and disposition decision on a returned dietary supplement; (3) The results of any testing or examination conducted to determine compliance with product specifications established under §111.70(e); and, (4) Documentation of the reevaluation by quality control personnel of any dietary supplement that is reprocessed and the determination by quality control personnel of whether the reprocessed dietary supplement meets product specifications established in accordance with §111.70(e).		
	Subpart O—Product Complaints		
	Written Procedures		
	You must establish and follow written procedures to fulfill the requirements of this subpart O.		
111.560	**Review and investigation of a product complaint**		
	(a) A qualified person must: (1) Review all product complaints to determine whether the product complaint involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part 111, including those specifications and other requirements that, if not met, may result in a risk of illness or injury; and (2) Investigate any product complaint that involves a possible failure of a dietary supplement to meet any of its specifications, or any other requirements of this part, including those specifications and other requirements that, if not met, may result in a risk of illness or injury. (b) Quality control personnel must review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed. (c) The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, must extend to all relevant batches and records.		
111.570	**Records**		
	(a) You must make and keep the records required under this subpart O in accordance with subpart P of this part. (b) You must make and keep the following records: (1) Written procedures for fulfilling the requirements of this subpart, (2) A written record of every product complaint that is related to good manufacturing practice, (i) The person who performs the requirements of this subpart must document, at the time of performance, that the requirement was performed. (ii) The written record of the product complaint must include the following: (A) The name and description of the dietary supplement; (B) The batch, lot, or control number of the dietary supplement, if available; (C) The date the complaint was received and the name, address, or telephone number of the complainant, if available; (D) The nature of the complaint including, if known, how the product was used; (E) The reply to the complainant, if any; and (F) Findings of the investigation and follow-up action taken when an investigation is performed.		

	Subpart P—Records and Recordkeeping		
111.605	**Records**		
	(a) You must keep written records required by this part for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of dietary supplements associated with those records. (b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. (c) All electronic records must comply with part 11 of this chapter.		
111.610	**Records that must be made available to FDA**		
	(a) You must have all records required under this part, or copies of such records, readily available during the retention period for inspection and copying by FDA when requested. (b) If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA.		

The Virginia Board of Pharmacy
Inspection

Processor Name		Permit Number		Date	

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The Virginia Board of Pharmacy
Inspection Summary

COMPLETE AND RETURN TO THE BOARD OFFICE WITHIN 14 DAYS OF THE INSPECTION.
SUBMIT BY U.S. MAIL, FAX (804-527-4472) OR EMAIL TO pharmbd@dhp.virginia.gov.
RETAIN A COPY FOR YOUR RECORDS.

Pharmacy Name		Pharmacy License Number		Date	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

The Virginia Board of Pharmacy
Inspection Summary

0

Pharmacy Name	0	Pharmacy License Number	0	Date	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

The Virginia Board of Pharmacy
Inspection Summary

Pharmacy Name	0	Pharmacy License Number	0	Date	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

The Virginia Board of Pharmacy
Inspection Summary

Pharmacy Name	0	Pharmacy License Number	0	Date	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	

No	Law/Regulation	Deficiency

Corrective Steps Taken	