



COMMONWEALTH of VIRGINIA

Department of Agriculture and Consumer Services

PO Box 1163, Richmond, Virginia 23218

www.vdacs.virginia.gov

Joseph W. Guthrie
Commissioner

Manufacturer of an Industrial Hemp-Derived Extract Intended for Human Consumption

General Information

Thank you for your inquiry regarding the production of an industrial hemp-derived extract intended for human consumption in Virginia. The following documents are enclosed/attached, or are available at the VDACS website for you:

- VDACS Permit Application – Industrial Hemp-Derived Extract Processing Operation
- Virginia Food and Drink Law
- 21 CFR 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- 2VAC5-595 Regulations Governing the Manufacturing and Sale of Products that Contain Industrial Hemp Extracts Intended for Human Consumption
- How To document for completing this application and preparing for your inspection
- Other information pertaining to your food business

If, after reviewing the application and other materials, you have any questions, please contact the VDACS Food Safety Program at 804-786-3520 or foodsafety@vdacs.virginia.gov.

Please be advised that pursuant to 2VAC5-595-30, a person that manufactures an industrial hemp extract in Virginia shall first be inspected by the department. An inspection of your operation will not be conducted until all of the necessary information requested in the permit application has been reviewed by the VDACS Food Safety Program office. You will be notified when this has been completed.

Also, there is a \$40.00 annual fee for operating an industrial hemp extract business. You will not be required to pay this fee at the time of your initial inspection; however, you will receive a bill during our next billing cycle.

Sincerely,

A handwritten signature in cursive script that reads "Pamela Miles".

Pamela Miles
Program Supervisor
Food Safety Program
Office of Dairy & Foods
Virginia Department of Agriculture & Consumer Services

**Permit Application for Manufacturer of an Industrial Hemp- Derived
Extract Intended for Human Consumption**

Date of Application:	Industrial Hemp Processor Registration Number:	County in which business is located:
Business Name:		
Owner Name:		
Phone:	Email Address:	
Processing Location Address:		
Business Mailing Address:		
Water Supply:	Public Private* Type (drilled, bored, etc) <small>*FOR A PRIVATE WATER SUPPLY, ATTACH A CURRENT WATER TEST REPORT SHOWING ABSENCE OF COLIFORM BACTERIA</small>	
Sewage Disposal:	Public Private* <small>*FOR A PRIVATE SEWAGE DISPOSAL SYSTEM, ATTACH DOCUMENTATION THAT YOUR SYSTEM IS APPROPRIATE</small>	
Pets (if operating in the home):	Yes No	
Number of employees, including owner:	Days and hours of operation:	
Percentage of ingredients received from out of state suppliers:	Percentage of products sold retail:	
Percentage of products sold to out of state customers:	Percentage of products sold wholesale:	

Checklist of Required Information

Documentation of zoning approval to operate a food processing business on the property
Documentation that the hemp-derived extracts intended for human consumption are produced from industrial hemp grown in compliance with federal or state law
Documentation that the hemp-derived extracts intended for human consumption have a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent
Provide a certificate of analysis if the label states that any amount of cannabinoids are present in the finished product
Diagram of processing and storage areas
If private water supply is used, a copy of water test results showing Coliform bacteria are "absent"
Documentation that the private sewage disposal system is adequate for intended use
Documentation of employee training
If operating in the home, provide written explanation of how contamination with personal belongings will be prevented
Written procedures for preventing allergen cross-contact
If applicable, additional documentation required under Subparts C & G under 21 CFR 117
List of all products submitted for review with planned method and place of distribution
List of all ingredients used in your business, with the source of each
Product information sheet for each product
Copy of label for each product

Application Instructions

1. Review the [How To document](#) for completing this application and preparing for your inspection.
2. Complete page 1, providing all of the requested basic business/owner information. Please do not submit your application without any of the required information as it will not be reviewed without it. Submit all of it together at the same time.
 - Note about pets in the home: If you marked “Yes”, areas where food is prepared, or stored, where packaging material is stored and where equipment is cleaned and stored must be completely enclosed/separated from the rest of the home in order to be considered for home based food manufacturing. Pets must be excluded from these areas at all times. For example, food processing and storage areas must be fitted with a solid hinged door(s) that can be latched/closed shut. Placing pets in closed rooms in other areas of the home or installing "baby gates" will not satisfy this requirement.
 - Note on hours of operation: inspections are unannounced and unscheduled. Provide a list of the weekdays and times that operation would normally occur. The inspector will visit for inspection during these hours.
3. Provide written documentation that you have approval from the locality’s zoning office to operate a food processing business on the property. Alternatively, if you are using a community kitchen, provide written documentation that you have the operator’s permission. Any verifiable documentation is acceptable, such as email correspondence, official letter or other.
4. Provide a diagram of the food processing and storage areas.
5. If the property is using a private water supply (e.g. well), you must provide evidence that the water is potable. A recent copy (less than six months old) of lab results showing that Coliform bacteria were “absent” in a sample of your well water is required. The testing laboratory that you use must be certified by the Virginia Safe Drinking Water Program. A list of labs that are certified for water testing can be found at this link: [Virginia Safe Drinking Water Certified Laboratories](#)
6. If private sewage disposal is used, obtain documentation from an Alternative Onsite Soil Evaluator (AOSE), Professional Engineer (PE) or Virginia Department of Health that your system is adequate for the intended use of your business. Please see <https://drive.google.com/open?id=1nIVtqik9hDqAfzsaJX8J35dnknIG3Svl&usp=sharing> for additional information and to locate a service provider. NOTE: All service providers must be properly licensed through the Department of Professional and Occupational Regulation (DPOR).
7. As a food manufacturer, you and any employees of your business must be trained, and you must provide documentation of said training. Provide documentation that you and any employees have received training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to your food products, your facility and the employee’s assigned duties. Even if the owner is the only employee, a training record needs to be maintained.
8. Provide a list of all products you plan to make, as well as the planned location of distribution.
9. Develop a written plan to prevent allergen cross-contact.
10. Provide a list of all of the ingredients you will be using, the source of those ingredients, and determine if any of the eight major allergens are present in each ingredient.
11. Complete a Product Information Sheet for each product you plan to make. Mark “Trade Secret” if your formulation/process is confidential. We will not share your process, but you must provide it.
12. Provide a copy of the label for each product (mock labels are acceptable if actual labels have not yet been made). Labels must comply with the labeling regulations, 21 CFR 101, and the requirements in 5VAC5-595.
13. Submit applications to the VDACS Food Safety Program. An incomplete application will cause delay in it being processed. Hand-written applications will not be accepted.
By email (preferred): foodsafety@vdacs.virginia.gov
By mail: ATTN: Food Safety PO Box 1163 Richmond, VA 23218
By fax: 804-371-7792
14. Once your application is submitted, it will be reviewed, and you will be contacted by the reviewer if there are any questions. When the application review is complete, a Food Safety Specialist will contact you to schedule the initial inspection.
15. If you do not provide a response to the reviewer’s comments within four months, your application will be discarded. A new application will need to be submitted if you wish to continue.

Requirements for Manufacturers of Industrial Hemp Extracts

In order to produce a hemp-derived extract intended for human consumption a registered hemp processor:

- Must be able to provide documentation that the hemp-derived extracts intended for human consumption are produced from industrial hemp grown in compliance with federal or state law.
- Must be able to provide documentation that the hemp-derived extracts intended for human consumption have a tetrahydrocannabinol (THC) concentration of no greater than 0.3 percent.
- Shall meet the standards stated below, which are standards that are included in the regulations promulgated by the Virginia Board of Pharmacy for the production of the cannabidiol oil product that it regulates.

Microbiologicals			
A hemp-derived extract intended for human consumption shall satisfy the standards set forth in Section 1111 of the United States Pharmacopeia.			
Mycotoxins		Heavy Metals	
Aflatoxin B1	<20 ug/kg of Substance	Arsenic	<10 parts per million (ppm)
Aflatoxin B2	<20 ug/kg of Substance	Cadmium	<4.1 ppm
Aflatoxin G1	<20 ug/kg of Substance	Lead	<10 ppm
Aflatoxin G2	<20 ug/kg of Substance	Mercury	<2 ppm
Ochratoxin A	<20 ug/kg of Substance		
Residual Solvents			
A hemp-derived extract intended for human consumption shall meet the standards and limits outlined in 2VAC5-595-50(I).			

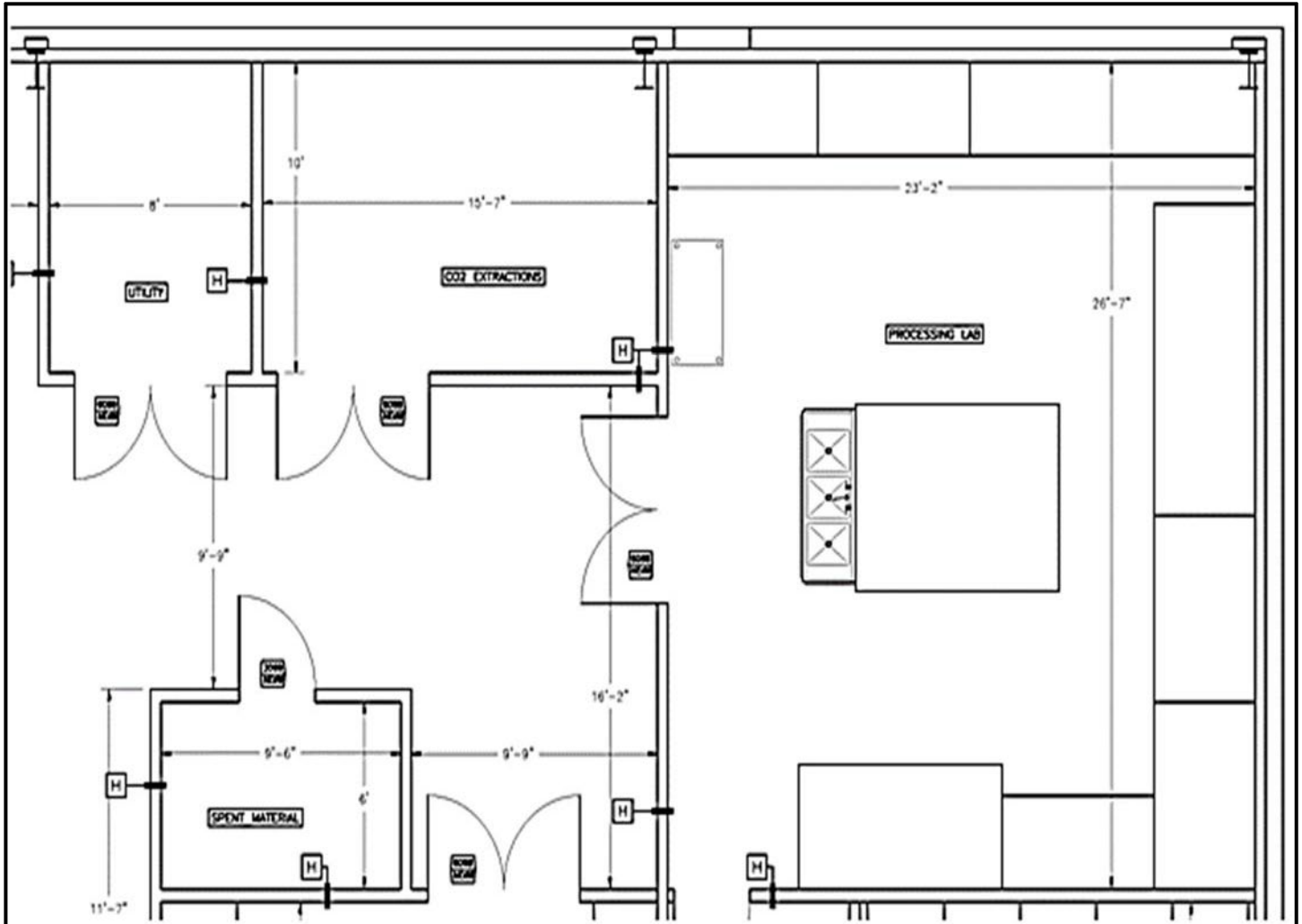
- Chemical residue from pesticides shall meet the standard for the pesticide chemical residue test established in 18VAC110-60-300.
 1. Pesticide chemical residue testing shall include testing for carbamates, organochlorines, and organophosphates.
 2. Pesticide application to industrial hemp or during the processing of industrial hemp must be done in accordance with the label of that pesticide and in compliance with the Virginia Pesticide Control Act (§ 3.2-3900 et seq. of the Code of Virginia) and any regulations adopted thereunder.
 3. Pesticide application records for the industrial hemp from which an industrial hemp extract is produced must be maintained for at least three years
- Must be able to provide a certificate of analysis if the label states that any amount of cannabinoids or phytochemicals, including a terpene or flavonoid, are present in the finished product.
- Laboratory analysis shall be performed by a lab that meets the requirements outlined in 2VAC5-595-50(E)
- Industrial hemp extract testing records must be maintained for at least three years
- Comply with the food laws and regulations pertaining to food manufacturing, including [21 CFR Part 117](#), Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.
- Comply with Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements ([21 CFR 111](#)) *if the industrial hemp-derived extract product appears to be labeled or marketed as a Dietary Supplement.*

Zoning/Commercial Kitchen Approval

Include your zoning approval or documentation of approval to use the kitchen for your business here or on a separate sheet.

Example: Diagram of food processing and storage areas

The diagram may be drawn using computer software or drawn by hand.



Food Processing and Storage Area Diagram

Include your diagram here or on a separate sheet. Clearly indicate or label each area used for storage of raw ingredients, packaging materials, finished products, processing area, warewashing facilities, handwashing sinks, restrooms, etc.

Employee Training and Records

As a food manufacturer, you and any employees of your business must be trained, and you must provide documentation of said training, in addition to keeping a record of this training. An adequate and complete training course would include topics on employee health and hygiene, proper food storage and cooking temperatures, cleaning food contact surfaces, allergen awareness/control and any other topics specifically applicable to your particular food processing operation.

List of available trainings (this list is not all-inclusive):

NC State Food Safety Education & Training

- Good Manufacturing Practices in Food Safety
- <https://units.cals.ncsu.edu/foodsafety/good-manufacturing-practices-in-food-safety/>
- (919) 513-2065

Institute for Food Safety at Cornell University

- Good Manufacturing Practices Part 117 Online Course
- <https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/>
- (315) 787-2288

360training.com, Inc.

- Learn2Serve Food Protection Manager Certification Program:
- <https://www.360training.com/>
- (877) 881-2235

AboveTraining/StateFoodSafety.com

- Certified Food Protection Manager (CFPM) Exam:
- <https://www.statefoodsafety.com/>
- (801) 494-1416

National Registry of Food Safety Professionals

- Food Manager Certification
- <https://www.nrfsp.com/>
- (800) 446-0257

National Restaurant Association

- ServSafe Food Protection Manager Certification Program
- <https://www.servsafe.com/>
- (800) 765-2122

The Always Food Safe Company, LLC

- Food Protection Manager Certification
- <https://alwaysfoodsafecom/en/>
- (844) 312-2011

Example template (please create a training record similar to this template and include a copy of it with your application):

Employee Training Record				
Grannie's Cookies 111 Happy Ln Anytown, VA 22554				
Employee Name	Course Name	Location	Date Completed	Trainer Signature

Employee Training and Records

Include a copy of your training record and documentation here or on a separate sheet.

Preventing Contamination from Personal Belongings*

The regulation states that clothing or other personal belongings cannot be stored in areas where food is exposed or where equipment or utensils are washed. You need to ensure that you can meet this requirement in your home kitchen. Personal belongings are any items that are not used in the manufacturing of your foods that will be offered for sale to the public. In addition, the regulation also states that eating food, chewing gum, drinking beverages or using tobacco cannot occur in areas where food is exposed or where equipment or utensils are washed. This means that during the hours that your home is used as a food manufacturing facility, all areas must have first been cleaned and sanitized and that all personal belongings must be removed from the countertop, tables, etc. where food will be manufactured. Compliance with these requirements will be verified by the inspector.

**This section is only required if you are processing in your home.*

Provide your written explanation describing how you will comply here or on a separate sheet.

Product List and Planned Distribution

Products submitted for review	Planned distribution

Preventing Allergen Cross-Contact

The eight major allergens in the U.S. are: milk, wheat, eggs, peanuts, tree nuts, soybeans, fish, and crustacean shellfish. Preventing accidental inclusion of allergens into products that should not contain them is critical to the safety of your food products. Cross contact occurs when an allergen from one food (walnuts, for example) is transferred to another food that does not contain the allergen (strawberry jam, for instance). You should conduct a food allergen ingredient analysis. If your analysis identifies food allergens that will (or may be) in your products, you must have controls in place that prevent allergen cross contact that includes all the products you manufacture for sale. When you operate in a space that is also used for other businesses, you must also consider foods that they store and prepare. Including a statement on your product label such as “may contain [peanuts], [tree nuts], [fish]...” is not an adequate control for preventing cross contact.

The following resources may help you in developing a plan:

- [Allergen Control Plan - Overview and Guidance](#)
- [Putting Together an Effective Allergen Control Plan, Food Safety Magazine October/November 2017](#)
- [Components of an Effective Allergen Control Plan](#)
- [FDA - What You Need to Know about Food Allergies](#)
- [FDA - Allergen Cross-Contact Prevention](#)

Provide your written plan for preventing allergen cross contact here or on a separate sheet.

Allergen Control Plan - Master List of Ingredients

Business Name and Address: _____ Date: _____

Food Allergen Ingredient Analysis Worksheet.

Raw Material Name	Supplier	Ingredients List for this Raw Material	Food Allergens in Ingredient Formulation							Allergens in Supplier's Precautionary Labeling
			Egg	Milk	Soy	Wheat	Tree Nut	Peanut	Fish	

How to Use the Chart
 List all ingredients received in the facility. Identify allergens contained in each ingredient by reviewing ingredient labels or contacting the manufacturer. Any allergens listed in "May contain" or other precautionary labeling on ingredients should be listed in the last column and reviewed to determine if allergen labeling is needed on the finished product.

Requirements of 21 CFR 117 Subparts C & G and Exemptions

Who is not subject to the requirements of Subparts C and G?

- A business conducting at least 50% of sales directly to the consumer (retail). This type of business does not need to register with the FDA and does not need to file a form 3942a (qualified facility attestation).
- Very small businesses that have attested to FDA. A very small business is one that averages less than \$1,000,000 in sales of human food per year for 3 years. Use the instructions and form 3942a at this website to submit your attestation: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-determination-status-qualified-facility>
- Facilities who exclusively handle or manufacture seafood, juice, dietary supplements, or alcoholic beverages. To clarify, if your facility handles any of the above products, plus other commodities, then you are subject to Subparts C and G.
- Home food processors

If you do not meet any of the above exemptions, you must comply with and submit the following:

Subpart C: Hazard Analysis and Risk-Based Preventive Controls

This subpart applies to all businesses not in the list above, which is the vast majority of food manufacturers. Facilities that are subject to this subpart must have a written and implemented Food Safety Plan (FSP). The FSP must be overseen by a Preventive Controls Qualified Individual (PCQI). The FSP must include the following:

● Hazard analysis	● Monitoring procedures
● Preventive controls	● Corrective action procedures
● Supply chain program	● Verification procedures
● Recall plan	

Preventive Controls Qualified Individuals (PCQI)

Preventive Controls Qualified Individual means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

For additional information visit: <https://www.ifsh.iit.edu/fspca>

Subpart G: Supply-Chain Program

This subpart outlines the requirements for a supply chain program. The safety of the product you manufacture not only depends on the controls you put in place, but the controls applied by your suppliers or your customers. If a known hazard exists in your product or ingredients, it needs to be controlled, whether that be at your supplier's facility, at your facility, or by the next facility in the supply chain. If you decide that the hazard will not be controlled at your facility, then you should identify a supply chain control in your hazard analysis. If you do so, you will need to implement supply-chain control which may include using approved suppliers and conducting verification of these suppliers.

Resources for Creating Your Food Safety Plan

- Food Safety Preventive Controls Alliance: <https://www.ifsh.iit.edu/fspca>
- FDA: <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>
- Virginia Tech Food Innovations Program: Joell Eifert, Director foodbiz@vt.edu or (540) 231-5770

Food Safety Plan and Supply-Chain Program

If you do not qualify for an exemption as explained above, include a copy of your Food Safety Plan and Supply-Chain Program here or on a separate sheet. If you are a very small business, include documentation you have attested.

Basic Labeling Requirements

The following are labeling components required for all packaged foods. Failure to provide labels as described below will cause your application to be returned. Refer to the labeling regulation 21 CFR 101 for complete details.

Product Name:

- Must be on the front panel
- Must be an accurate description of the product
- metric units Must be in bold print
- Must be the largest type on the panel

Net Weight:

- Must be on the front panel
- Must be stated in both standard and
- Must be in bold print
- Must be located on the bottom of the panel

Ingredients Statement: Must appear on the same panel as the name and address of your business. It must be on the front panel or the panel directly to the right of the front panel. Ingredients must be listed in order of heaviest to least heavy. If any ingredient is made of two or more ingredients, these “sub-ingredients” must be listed in parentheses next to the main ingredient. When one of the eight major food allergens is an ingredient or sub-ingredient, it must be identified by name, either within the ingredient statement OR in a separate statement directly below the ingredient statement. This is called a “contains statement” and must follow the format shown below. The only words that may be used to identify the allergens are the following: Milk, Wheat, Eggs, Peanuts, Tree Nuts (name the specific type of nut), Soybeans, Fish (name the specific species of fish), and Crustacean Shellfish (name the specific species of crustacean).

Allergens* listed in ingredient statement:

Ingredients: Hemp Seed Oil, Coconut Oil, Full Spectrum Hemp Extract.

OR

Allergens* listed in contains statement:

Ingredients: Hemp Seed Oil, Coconut Oil, Full Spectrum Hemp Extract. Contains: Coconut

Name and Address of Manufacturer, Distributor, or Packer: Must appear on the same panel as the ingredient statement. It must be on the front panel or the panel directly to the right of the front panel. The address of the business must be listed in full—street name, city, state and zip. A PO Box, telephone number, email address, website address or other cannot substitute.

Industrial Hemp Extract and Foods Containing an Industrial Hemp Extract Labeling Requirements

The following are the additional labeling components required for industrial hemp extracts and foods containing an industrial hemp extract. Failure to provide labels as described below will cause your application to be returned. Refer to section 60 of 2VAC5-595 for complete details.

Cannabinoid Declaration	If your product is labeled as containing a specific cannabinoid or concentration thereof, the number of milligrams of such cannabinoid must be declared on the product label. You must also maintain records verifying the declared amount of cannabinoid.
Batch Code	Each batch shall be identified with a unique code for traceability. Julian date coding or any other system developed and documented may be used.
Tetrahydrocannabinol Content	<p>If your product contains tetrahydrocannabinol (THC) in any amount, your label must contain the following:</p> <ul style="list-style-type: none"> A statement that the product contains THC and may not be sold to a person younger than 21 years of age; The amount of extract or food containing an industrial hemp extract that constitutes a single serving; and The total percentage and milligrams of THC included in the extract or food containing an industrial hemp extract and the number of milligrams of THC that are contained in each serving.

EXAMPLE LABEL

Full Spectrum Hemp Extract		
500mg CBD		
Serving size: 1mL 2mg THC per serving 60mg total THC 0.20% total THC		
Ingredients: Hemp Seed Oil, Fractionated Coconut Oil, Full Spectrum Hemp Extract.		
Grassy Fields Hemp Company LLC 14740 Country Road Somewhere, VA 24019		
Batch: 029	1 fl oz (30 ml)	May not be sold to persons younger than 21.

No claims can be made on the product label to the product's suggested use or potential health benefits unless you intend to comply with the dietary supplement regulation, 21 CFR 111 (in addition to 21 CFR 117). No claims can be made suggesting the product is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, as statements indicating such use would cause the product to be classified as a drug, as defined in 21 USC § 321(g)(1). Please be aware that labeling includes statements or images on the product packaging, business website or social media, flyers, newsletters or any other form of product marketing not explicitly mentioned here.

Note: If your product will be a dietary supplement, additional labeling requirements will be applicable. Please contact VDACS Food Safety for more information.

Product Information Sheet

Business Name:		Date:	
Product Name:		Trade Secret:	

List of Ingredients (Include quantity of each, preferably by weight in ALL ounces or ALL grams):

Step-by-Step Processing Procedures from raw ingredients to finished product:

Product Label

Include a copy of your label here or on a separate sheet.