SELECT PLANT-BASED
DERIVATIVE PRODUCTS

# HEMP AND KRATOM PRODUCTS GUIDE

2023

November 2023 v.1.3

**West Virginia Hemp and Kratom Products Guide**

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*This document is updated when revisions to legislation, rules or other authorities occur.*

# Introduction

The West Virginia Hemp and Kratom Products Guide was developed to provide standards, guidelines and consistent information for manufacturers, retailers and distributors of hemp and kratom products that may be sold at various locations and the conditions that must be met at the point of sale.

**In West Virginia the level of total THC in industrial hemp and any hemp product (Cannabis sativa L.) must be no greater than 0.3 percent.**

**The legal limit of 7-7-hydroxymitragynine in a kratom product must be no greater than 2.0 percent.**

All manufacturers of hemp and kratom products, excluding hemp fiber products, available for distribution in West Virginia shall register annually with the West Virginia Department of Agriculture. This includes products manufactured in West Virginia, another state, or another country.

**Contact the West Virginia Department of Agriculture if you need assistance with registration at hempproducts@wvda.us or 304-558-2227.**

## HEMP PRODUCTS

Industrial hemp can be used in an estimated 50,000 different products across a wide spectrum of industries: from textiles to food products, building materials to bio-plastics, nutraceuticals to nanomaterials, ethanol to animal bedding. Cannabis oil/extract, hemp oil/extract, full spectrum hemp extracts, broad spectrum extract, and CBD isolate can all be found in a wide variety of products such as: tinctures, capsules, topicals (lotion/balm), suppositories, edible products, products that can be inhaled. Each consumption method has unique benefits & allows customers to select products based upon unique needs and desires.

**Some traditional categories of hemp products include:**

- Hemp concentrates or extracts
- Hemp edibles and drinks
- Hemp tincture
- Hemp topicals and lotions
- Hemp transdermal patches
- Hemp fiber/fiber products
- Hemp seed processed such that it is incapable of germination and processed such that is suitable for human consumption
- Hemp seed pressed or otherwise processed into oil
- Hemp aerosols
- Hemp vaping products
- Smokable hemp products that are properly packaged, labeled, and sealed in a manner approved by the Commissioner
- Pet treats or by-products used in animal feed

*** As federal regulations change, modifications may occur within the guidance document to better align with federal guidance on pet treats and by-products used in animal feed. Revisions to this document will be posted to the West Virginia Department of Agriculture's website.**

The term **hemp product** or **hemp commodity** does not include hemp that has not been processed in any form, hemp that has been minimally processed, for purposes of transfer or storage, including chopping, separating, or drying, and agricultural hemp seed.

West Virginia allows the manufacturing, distribution, dispensing, delivery, sale, purchasing, or possession of smokable hemp, THC-A flower must be under 0.3% total THC.

## KRATOM PRODUCTS

Kratom (Mitragyna speciosa) is a tropical evergreen tree from Southeast Asia and is a member of the Rubiaceae family. Other members of the Rubiacae family include coffee and gardenia. In the US, kratom has gained recent popularity for health benefits although this has not been clinically determined by the US FDA. Traditionally kratom leaves have been used in Southeast Asia for centuries. Kratom can be consumed as crushed leaves (eaten or smoked), tea, capsules or powder form.

**Kratom can come in forms as:**

- Tinctures
- Extracts
- Capsules/Tablets
- Raw Leaf/Flower
- Powder
- Teas
- Edibles


## DEFINITIONS AND COMMON ABBREVIATIONS

**Cannabidiol or CBD** means the compound by the same name derived from the hemp variety of the Cannabis sativa L. plant.

**Cannabinoid or Phytocannabinoid** means any of various naturally occurring, biologically active, chemical constituents (such as cannabidiol or cannabinol) of hemp or cannabis including some (such as THC) that possess psychoactive properties.

**Certificate of analysis or COA** means certificate issued by a laboratory that operates under ISO 17025:2017 management and laboratory practices, describing the results of the laboratory testing of the sample.

**Commercial sales** mean the sale of products in the stream of commerce direct to the endpoint consumer.

**Commissioner** means the Commissioner of Agriculture or his or her designee.

**Consumable** means a select plant-based derivative product intended for human and/or animal consumption.

**Crop** means hemp or Mitragyna speciosa grown under a single registration.

**Cultivating** means planting, watering, growing, and harvesting a plant or crop.

**Department** means the West Virginia Department of Agriculture and its employees.

**Distributor or Seller** means any person who sells, exposes for sale, offers for sale, exchanges, barters, gives, parcels out, allots shares, or dispenses a select plant-based derivative product.

**Fiber Product or Hemp Fiber Product** means a product that is manufactured with suitable fiber for textiles, rope, paper, hempcrete, or building or fiber materials.

**Grower** means a person, joint venture, cooperative, or any entity that produces select plant-based derivatives.

**“GRAS” or “GRAS status”** means an acronym for the phrase Generally Recognized As Safe, which is a status determined by the FDA.

**Handling** means possessing or storing hemp or Mitragyna speciosa plants for any period of time on premises owned, operated, or controlled by a person licensed to cultivate or process hemp or Mitragyna speciosa. Handling also includes possessing or storing hemp or Mitragyna speciosa plants in a vehicle for any period of time other than during its actual transport from the premises of one licensed person to cultivate or process hemp or Mitragyna speciosa to the premises of another licensed person. Handling does not mean possessing or storing finished hemp products.

**Hemp** means all parts and varieties of the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not with no greater than a total THC of 0.3% tetrahydrocannabinol, or the THC concentration for hemp defined in 7 U.S.C. § 5940, whichever is greater.

**Hemp products** means all products derived from, or made by, processing hemp plants or plant parts, that are prepared in a form available for commercial sale.

**Informational panel** means any part of the label that is not the primary label.

**Intended for human consumption** means to ingest, inhale, or topically apply to the skin or hair.

**Kratom** means any portion of the specified strain of botanical Mitragyna speciosa.

**Kratom product** means any product manufactured from any part of the Mitragyna speciosa plant, containing the alkaloids mitragynine and 7-hydroxymitragynine and intended or marketed for consumption.

**Licensee** means any person or business entity possessing a license issued by the Department to grow, handle, cultivate, or process hemp or Mitragyna speciosa.

**Lot** means any amount of hemp or Mitragyna speciosa product of the same type and processed at the same time using the same ingredients, standard operating procedures, and batches.

**Manufacturer or processor** means a person or entity who is processing, compounding, or converting raw hemp or Mitragyna speciosa into a commodity or product.

**Primary label** means the part of the label to be prominently displayed to the consumer at retail.

**Processing** means converting an agricultural commodity into a marketable form.

**Registrant** means a person or entity that has registered hemp or Mitragyna speciosa products with the Department.

**THC** means tetrahydrocannabinol and is used interchangeably with “Total THC”. “Total THC” means the quantifiable amount of delta-nine THC plus 0.877% of the amount of tetrahydrocannabinolic acid in a product.

**THC-free or Non-THC** means a hemp product that contains less than a detectable or quantifiable amount per serving of tetrahydrocannabinol.

**Total THC** = THC delta 9 + (THCA x 87%)

**White Label** means a manufactured hemp or Mitragyna speciosa product that is manufactured or produced by one person or entity but sold by another person or entity under their own label.

# REGISTRATION TO DISTRIBUTE AND SELL HEMP AND KRATOM PRODUCTS OR EXTRACTS

All retail facilities, including online locations, are required to register with the Department to sell hemp and kratom products in West Virginia. Each retail establishment site must register annually.

Application to sell and distribute hemp and kratom products shall be made to the Department on a form provided by the Department and shall include the following information:

- Name and address of the applicant's retail store; or, if the applicant is selling at an on-line store, this must be indicated on the form.
- Name and home address of the responsible party
- The associated registration fee
- Tax Identification number or FEIN
- Letter of good standing with WV Tax Division

For hemp retailers and distributors: an annual registration fee of $100.00 per location shall be paid to the Department with the submission for application to sell and distribute hemp products in West Virginia, unless the retail facility or distributor is only selling hemp fiber products.

For kratom retailers: an annual registration fee of $300.00 and a one-time application fee of $1,500.00 shall be paid to the Department with the submission for application to sell and distribute kratom products in West Virginia.

A registration fee shall be paid annually. Beginning January 1, registrations shall expire on December 31 of the year for which the registration was issued, regardless of the date the registration is received.

Retail establishments that sell only products that they manufacture themselves are exempt from the requirement to pay the fee to distribute but are not exempt from the requirement to register annually.

Retail facilities that register with the Department will be provided a verification document, in the form of a certificate or otherwise, for display at the retail location, which will indicate that the retail facility is an authorized location for the sale and/or distribution of hemp products.

The Department may deny or delay registrations for incomplete applications.

All retail establishments must submit a letter of good standing from the WV Tax Division.

The following hemp derived cannabinoids are subject to an additional 11% excise tax paid quarterly to the WV Tax Division:

- Delta-10-Tetrahydrocannabinol (Delta-10-THC)
- Delta-9-tetrahydrocannabinol (THC) <0.3% Total THC
- Delta-8-tetrahydrocannabinol (Delta-8-THC)
- Delta-9-tetrahydrocannabivarin (THCv)
- Hexahydrocannabinol (HHC) (-)
- Tetrahydrocannabiphorol (THCp)
- All kratom products

# REGISTRATION OF HEMP AND KRATOM PRODUCTS

All hemp and kratom products available for distribution in West Virginia shall register annually with the Department. This includes products manufactured in West Virginia, another state, or another country.

Application for hemp and kratom products shall be made to the Department on a form provided by the Department, and shall include the following information in the registration packet:

- The name and address of the applicant
- The name and address of the person whose name shall appear on the label, if other than the applicant's
- The name of the product
- The name and address of the origin of the raw hemp or kratom product with which the final product was manufactured
- A complete copy of the label that will appear on the product
- The associated registration fee.

A registration fee shall be paid annually. Beginning January 1, registrations shall expire on December 31 of the year for which the registration was issued, regardless of the date the registration is received.

**For hemp product manufactures:** an annual registration fee of $200.00 per hemp product shall be paid to the Department with the submission of the application. Once an individual product is registered with the WVDA and approved, it may be sold by any registered seller or vendor in the state.

**Hemp products are defined as all products derived from, or made by, processing hemp plants or plant parts, that are prepared in a form available for commercial sale. In West Virginia the level of total THC in hemp and any hemp product (Cannabis sativa L.) must be no greater than 0.3 percent.**

**For kratom product manufacturers and distributors:** an annual registration fee of $300.00 and a one-time application fee of $1,500.00 shall be paid to the Department with the submission for application to sell and distribute kratom products in West Virginia. Beginning January 1, 2025 all kratom products will be registered at $200 per product.

Beginning January 1, 2022, in lieu of the $200.00 hemp products registration fee stated, an annual registration fee of $100.00 per hemp product shall be paid to the Department with the submission of the application, if the hemp material(s) are grown, harvested, and manufactured in West Virginia and the products are registered with the West Virginia Grown program (see WV Grown application).

Hemp products that are registered under the $100/per product registration of this rule must include a copy of the registrant's West Virginia processing/cultivation license, or records of where the product was cultivated and processed in West Virginia and WV Grown acceptance.

A renewal fee of $200.00 per hemp product shall be submitted to renew a product's registration. Renewal fees shall be accompanied by a form provided by the Department identifying the product to which the fee corresponds.

A renewal fee of $100.00 per hemp product shall be submitted to renew a product's registration if the hemp material(s) are grown, harvested, and manufactured in West Virginia and the products are registered with the West Virginia Grown program. Renewal fees shall be accompanied by a form provided by the Department identifying the product to which the fee corresponds.

The annual fee for hemp product registrations shall be capped at $1,000.00 per registrant for products that are manufactured and sold in West Virginia.

The annual fee for hemp product registrations that are white labeled by a West Virginia vendor for sale in West Virginia shall be capped at $2,000.00 per vendor. White labelers must use West Virginia grown hemp in order to be eligible for the cap of $2,000.00. The white labeler is subject to all fines and enforcement actions related to the white labeled products.

Beginning January 1, 2022, in lieu of the $1,000.00 registration cap fee stated for the product registration of this rule, a registration cap fee of $500.00 per registrant shall be paid for hemp and kratom products that are grown, harvested, manufactured in West Virginia, and registered with the WV Grown Program.

Hemp or kratom products that are of the same chemical composition but of different quantities qualify as one product.

Hemp or kratom product registrations that come from an international entity shall be required to pay a foreign check fee of $35.00.

The Department may deny or delay registrations and renewals that are incomplete.

A new registration is required for any of the following:

- Changes in the chemical composition or formula of the hemp product.
- Changes to health-related label claims for active ingredients.

The person registering the product is responsible for the completeness and accuracy of all information submitted.

A retailer, distributor, or registrant may register a product in lieu of the product manufacturer if the product is not registered.

As a condition of registration, all manufacturers and registrants are required to retain documentation for each product lot demonstrating the source of the hemp that was utilized to manufacture the hemp product, including documentation that the product was grown by a licensed hemp grower. Such documentation shall be made available to the Department upon request.

**Kratom refers to both Mitragyna speciosa, a tree native to Southeast Asia, and to products derived from its leaves that are marketed as herbal supplements. Kratom leaves contain many chemical compounds (known as bioactive alkaloids) that can affect the body.**

## West Virginia Hemp Products Quick Reference Guide

The quick guide below may be used to assist in the determination and requirements for hemp product registrations in West Virginia.

| Hemp Product | Required Registration? Yes / No | Required Fee? Yes / No | Label Required with Registration? Yes / No |
|---|---|---|---|
| **Textiles** | Yes | No | No |
| **Rope** | Yes | No | No |
| **Paper** | Yes | No | No |
| **Hempcrete** | Yes | No | No |
| **Fiber** | Yes | No | No |
| **CBD Oil** | Yes | Yes | Yes |
| **Seed Derivative** | Yes | Yes | Yes |
| **Concentrate or Extracts** | Yes | Yes | Yes |
| **Edibles** | Yes | Yes | Yes |
| **Drinks** | Yes | Yes | Yes |
| **Tinctures** | Yes | Yes | Yes |
| **Topicals** | Yes | Yes | Yes |
| **Lotions** | Yes | Yes | Yes |
| **Transdermal Patches** | Yes | Yes | Yes |
| **Hemp Seed Edibles** | Yes | Yes | Yes |
| **Hemp Seed Oil** | Yes | Yes | Yes |
| **Aerosols** | Yes | Yes | Yes |
| **Vaping Products** | Yes | Yes | Yes |
| **Smokable Hemp / Flower / Bud** | Yes | Yes | Yes |
| **Pet Treats / Food** | Yes | Yes | Yes |
| **Pet Supplements** | Yes | Yes | Yes |
| **Products that are not consumed, inhaled, ingested, or come in contact with skin** | Yes | No | No |

## Certificate of Analysis

**The Department does not require a certificate of analysis however, may conduct audits without notice at the Departments discretion.**

The certificate of analysis for all products, excluding hemp fiber products, shall minimally include the following information:

- A batch or lot number identification.
- The date the certificate of analysis was received.
- The method of analysis for each test conducted.
- The product name.

The certificate of analysis for all products containing CBD or THC products shall additionally minimally include the following test results:

- The cannabinoid profile by the percentage of dry weight which must include THC and CBD content
- Solvents
- Pesticides
- Microbial contaminants
- Heavy metals

## Hemp and Kratom Product Labeling

Hemp and kratom products for human consumption as a food or dietary supplement shall be labeled in accordance with FDA guidelines for food or dietary supplement labeling.

Hemp and kratom products produced for topical absorption by humans shall be labeled in accordance with FDA guidelines for Cosmetic Products Warning Statements.

Hemp and kratom products shall not contain disease or drug claims on the label that are not approved by the FDA.

The product lot on the label must be traceable to the plant origin.

Hemp products meant for animal consumption shall be labeled and comply with the West Virginia Commercial Feed Law, West Virginia Code §19-14-1 et seq.

Hemp seed products intended for cultivation shall be labeled in accordance with the West Virginia Seed Law, West Virginia Code §19-16-1 et seq.

Product labels must be clear and legible. Labels must be printed in English.

The following labeling is forbidden:

Unless at least 51% of the hemp or kratom in the product is grown in the state of West Virginia, the hemp or kratom product cannot be labeled as a West Virginia product.

- The product cannot be attractive to children. This includes, but is not limited to:
  - The use of cartoons.
  - The use of images popularly used to advertise to children.
  - The imitation of a candy or food label.
- The label cannot include false or misleading information. This includes untrue or unproven information that leads consumers to have an inaccurate impression.
- The label cannot include the use of the word “organic” unless the product has been certified as organic in accordance with the National Organic Program, as provided for by the USDA.
- Hemp product labels will be considered misbranded when a Department analysis finds the claim is above or below 20% of the cannabinoid amount declared on the label. Kratom product labels will be considered misbranded when a Department analysis finds the claim is above or below 20% of the alkaloid amount declared on the label. This shall remain effective through January 1, 2025. Excluding any tetrahydrocannabinols.

The following requirements must be met for the **primary label:**

- The product must be identified with the generic or common name.
- If the product contains any amount of cannabinoid(s) and/or mitragynine 7-hydroxymitragynine, the label must properly identify them.
- 7-hydroxymitragynine may not be sold in concentrations higher than two percent.

The following requirements must be met for the **information panel:**

- Manufacturer's name and contact information.
- Manufacturing or packaging date.
- Batch or lot number.
- Instructions for use and any preparation needed.
- List of all ingredients in descending order by weight or volume.
- Allergens if applicable.
- Artificial food coloring, if applicable.
- Expiration or use by date, if applicable.
- Refrigeration or refrigerate after opening warnings, if perishable after opening.
- For edible products, sodium, sugar, carbohydrates, and total fat per serving.
- The net weight or volume of the contents of the package, in both metric and US customary units must be displayed.

    - For capsules, soft gels, or similar products the net quantity of contents statement can be weight, volume, numerical count, or a combination of numerical count and weight or volume.

The cannabinoid, mitragynine, or 7-hydroxymitragynine content, in milligrams, may be posted on either the primary or informational panel, and must include:

- Any product label claiming a guaranteed cannabinoid, mitragynine, or 7-hydroxymitragynine (if applicable) shall provide the total amount of the claimed cannabinoid content per package for all the manufactured products; and Cannabinoid, mitragynine, or 7-hydroxymitragynine (if applicable) content per serving for all hemp and kratom products, with designated serving sizes.
- Any product containing hemp derived cannabinoids or kratom derivatives must declare on the label "NOT INTENDED FOR SALE TO PERSONS UNDER THE AGE OF 21; Keep out of the reach of children. Consult your physician before use if you are pregnant or taking any medication" and "Use of this product may impact drug testing results.
- It is unlawful to manufacture, package, import, distribute, or sell any hemp derived or kratom product without the required warning statements. The warning statement shall be printed in English in a conspicuous and legible type on the outer packaging.
- A temporary provision shall be made until January 1, 2025, on the above subsection 8.14 statement requirement on packaging, so long as the seller prominently displays a sign with the warning listed until all labels and packaging are compliant, except for "Not intended for sale to persons under the age of 21.
- A QR code, or similar tool, may be used in lieu of labeling requirements on the physical label's informational panel for all required information except that required by subsection 8.13 and 8.14 and subdivision 8.14.a and 8.14.b of §61-30-8 (the above three bullets).

# Hemp & Kratom Product Labeling - Food

**FROM FDA'S FOOD LABELING GUIDE: https://www.fda.gov/food/dietary-supplements- guidance-documents-regulatory-information/dietary-supplement-labeling-guide**

**What name and address must be listed on the label?**

Food labels must list:

- Name and address of the manufacturer, packer or distributor. Unless the name given is the actual manufacturer, it must be accompanied by a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for" or "distributed by").
- Street address if the firm name and address are not listed in a current city directory or telephone book.
- City or town.
- State (or country, if outside the United States).
- ZIP code (or mailing code used in countries other than the United States). 21 CFR 101.5.

**What is the name of the food statement called and where must it be placed?**

The statement of identity is the name of the food. It must appear on the front label, or PDP as well as any alternate PDP. 21 CFR 101.3.

**Should the statement of identity stand out?**

Use prominent print or type for the statement of identity. It shall be in bold type. The type size must be reasonably related to the most prominent printed matter on the front panel and should be one of the most important features on the PDP. Generally, this is considered to be at least 1/2 the size of the largest print on the label. 21 CFR 101.3(d).

**What name should be used as the statement of identity?**

The name established by law or regulation, or in the absence thereof, the common or usual name of the food, if the food has one, should be used as the statement of identity. If there is none, then an appropriate descriptive name, that is not misleading, should be used. Brand names are not considered to be statements of identity and should not be unduly prominent compared to the statement of identity. 21 CFR 101.3(b) & (d).

**Where should the statement of identity be placed on the label?**

Place the statement of identity on the PDP in lines generally parallel to the base of the package. 21 CFR 101.3(d).

**Are there restrictions on label artwork?**

Do not use artwork that hides or detracts from the prominence and visibility of required label statements or that misrepresents the food. 21 CFR 1.21(a)(1), 21 CFR 101.3(a), 21 CFR 101.105(h).

**Where should the country of origin be declared on an imported food?**

The country of origin statement must be conspicuous. If a domestic firm's name and address is declared as the firm responsible for distributing the product, then the country of origin statement must appear in close proximity to the name and address and be at least comparable in size of lettering. (FDA/CBP (Customs and Border Protection) Guidance and Customs regulation 19 CFR 134).

**Are foreign language labels permitted?**

If a foreign language is used anywhere on the label, all required label statements must appear both in English and in the foreign language. 21 CFR 101.15(c)(2).

**Where is the net quantity of contents statement placed on the label?**

The net quantity statement (net quantity of contents) is placed as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container. 21 CFR 101.105(e); 21 CFR 101.105(f).

**Should the net quantity of contents be stated in both grams and ounces?**

Food labels printed must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms. The metric statement may be placed either before or after the U. S. Customary statement, or above or below it. Each of the following examples is correct (additional examples appear in the regulations). P.L. 102- 329, August 3, 1992; 21 CFR 101.105.

- Net wt 1 lb 8 oz (680g)
- Net wt 1 lb 8 oz 680 g
- 500 ml (1 pt 0.9 fl oz)
- Net contents 1 gal (3.79 L)

**What is included in the net quantity of contents statement?**

Only the quantity of food in the container or package is stated in the net quantity statement. Do not include the weight of the container, or wrappers and packing materials. To determine the net weight, subtract the average weight of the empty container, lid and any wrappers and packing materials from the average weight of the container when filled with food. 21 CFR 101.105(g).

Filled container weighs - 18 oz.

Empty container weighs - 2 oz.

Wrapper weighs - 1 oz.

**Net Weight - 15 oz. (425 g)**

**INGREDIENTS LIST**

**What is the ingredient list?**

The ingredient list on a food label is the listing of each ingredient in descending order of predominance. “INGREDIENTS: Pinto Beans, Water, and Salt” 21 CFR 101.4(a).

**What is meant by the requirement to list ingredients in descending order of predominance by weight?**

Listing ingredients in descending order of predominance by weight means that the ingredient that weighs the most is listed first, and the ingredient that weighs the least is listed last (see illustration for question 3 below). 21 CFR 101.4(a).

**Where is the ingredient list placed on the label?**

The ingredient list is placed on the same label panel as the name and address of the manufacturer, packer or distributor. This may be either the information panel or the PDP. It may be before or after the nutrition label and the name and address of the manufacturer, packer or distributor. 21 CFR 101.4 See also section 3, question 7 of this guidance for information on intervening material on the information panel.

**COLOR:**

**What ingredient listing is used for vegetable powder?**

Vegetable powders must be declared by common or usual name, such as “celery powder.” 21 CFR 101.22(h)(3).

**What listing is used for a spice that is also a coloring?**

Spices, such as paprika, turmeric, saffron and others that are also colorings must be declared either by the term “spice and coloring” or by the actual (common or usual) names, such as “paprika.” 21 CFR 101.22(a)(2).

**What ingredient listing is used for artificial colors?**

It depends on whether the artificial color is a certified color:

Certified colors: List by specific or abbreviated name such as “FD&C Red No. 40” or “Red 40.”

Noncertified colors: List as “artificial color,” “artificial coloring,” or by their specific common or usual names such as “caramel coloring” and “colored with beet juice.”

21 CFR 101.22(k)(1) and (2), 21 CFR 74.

**Do certified color additive lakes have to be declared separately from the certified color in the ingredient statement?**

Yes. Certified color additives and their lakes are separate ingredients and, thus, must be declared separately in the ingredient statement. 21 CFR 101.22 (k)(1).

**FOOD ALLERGEN LABELING**

**What is the Food Allergen Labeling and Consumer Protection Act of 2004?**

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (or Title II of Public Law 108- 282) is a law that was enacted in August 2004. Among other issues, FALCPA addresses the labeling of all packaged foods regulated by the FDA. We recommend that producers of meat products, poultry products, and egg products, which are regulated by the U.S. Department of Agriculture (USDA), contact appropriate USDA agency staff regarding the labeling of such products. Also see Information about Food Allergens for more information about the agency’s food allergen activities and related guidance documents that address additional FALCPA questions and answers. http://www.fda.gov/Food/LabelingNutrition/FoodAllergensLabeling/default.htm

**What is a “major food allergen?”**

Under FALCPA, a “major food allergen” is an ingredient that is one of the following nine foods or food groups or an ingredient that contains protein derived from one of them:

1. milk
2. egg
3. fish
4. Crustacean shellfish
5. tree nuts
6. wheat
7. peanuts
8. soybeans
9. sesame

Although more than 160 foods have been identified to cause food allergies in sensitive individuals, the "major food allergens" account for 90 percent of all food allergies. Allergens other than the major food allergens are not subject to FALCPA labeling requirements.

**NUTRITION LABELING:**

**Where should the Nutrition Facts label be placed on food packages?**

The Nutrition Facts label may be placed together with the ingredient list and the name and address (name and address of the manufacturer, packer, or distributor) on the PDP. These three label statements also may be placed on the information panel (the label panel adjacent and to the right of the PDP, or, if there is insufficient space on the adjacent panel, on the next adjacent panel to the right). On

packages with insufficient area on the PDP and information panel, the Nutrition Facts label may be placed on any alternate panel that can be seen by the consumer. 21 CFR 101.2(b) & (e) & 101.9(i).

**Can the product name be placed within the Nutrition Facts label?**

No. The name may be placed above the box that encloses the nutrition information. 21 CFR 101.9(c) &

(d).

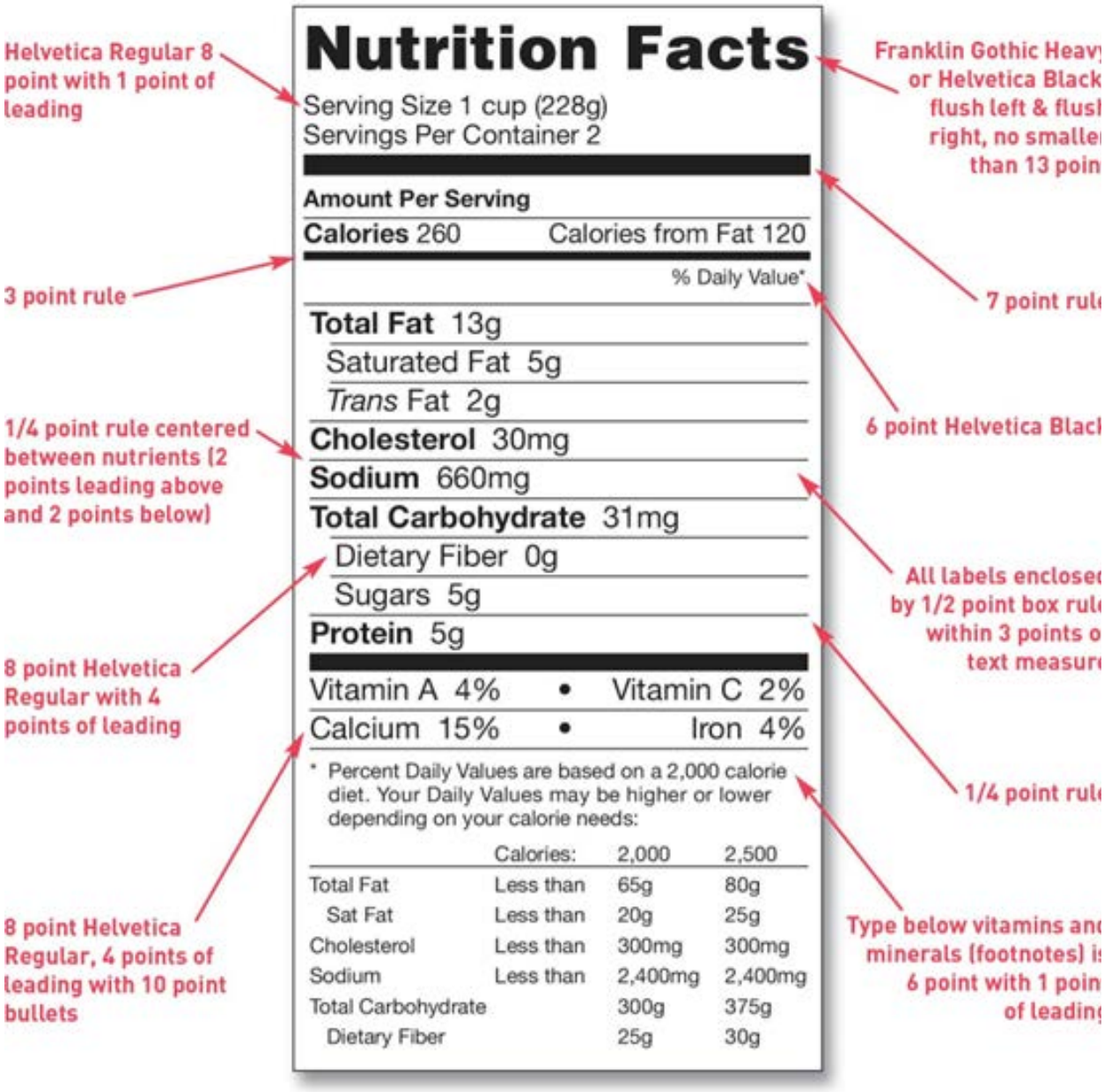
**How large must the Nutrition Facts label be?**

There are no specific size requirements for the nutrition label. However, the "Nutrition Facts" heading must be in a type size larger than all other print size in the nutrition label and generally set the full width of the nutrition facts label (21 CFR 101.9(d)(2)). Minimum type sizes of 6 point and 8 point are required for the other information in the nutrition label (21 CFR 101.9(d)(1)(iii)), and there are minimum spacing requirements between lines of text (21 CFR 101.9(d)(1)(ii)(C)).

**What are the minimum type sizes and other format requirements for the Nutrition Facts label?**

Format requirements are specified in 21 CFR 101.9(d). For example, the nutrition information must be set off in a box by use of hairlines and must be all black or one color type, printed on a white or other neutral contrasting background whenever practical. 21 CFR 101.9(d)(1)(i)

FDA urges that the nutrition information be presented using the graphic specifications set forth in appendix B to part 101 (see below).



**If a retail establishment produces $51,000 worth of food, but had a total gross sales for all products, food and nonfood, of $490,000, do they need a nutrition label?**

No. The firm is exempt provided that no claims are made. A firm whose total gross sales for all products, food and non-food, is $501,000, with only $49,000 of this figure representing sales of food, is also exempt. Under the NLEA, firms who have an annual gross sales made or business done in sales to consumers that is not more than $500,000 or have annual gross sales made or business done in sales of food to consumers of not more than $50,000 are exempt under 21 CFR 101.9(j)(1)(i).

The following chart illustrates the exemption:

| Sales in Food to Consumers | Total Sales (Food & NonFood) | Status |
|---|---|---|
| $50,000 or less | $500,000 or less | Exempt |
| $50,000 or less | $500,001 or more | Exempt |
| $50,001 or more | $500,000 or less | Exempt |
| $50,001 or more | $500,001 or more | Not Exempt |

**What type of records need to be kept to a substantiate a small business exemption, and will FDA be maintaining copies of any records for this exemption?**

It is up to each company to maintain records, such as tax forms, to support such an exemption. FDA will not maintain such records.

**Are abbreviations permitted in Nutrition Facts labels for small and intermediate sized packages?**

Food packages with a surface area of 40 sq. in. or less available for labeling may use the following abbreviations in the Nutrition Facts label:

| Label Term | Abbreviation | Label Term | Abbreviation |
|---|---|---|---|
| Serving Size | Serv Size | Cholesterol | Cholest |
| Servings per Container | Servings | Total carbohydrates | Total carb |
| Calories from fat | Fat cal | Dietary fiber | Fiber |
| Calories from saturated fat | Sat fat cal | Soluble fiber | Sol fiber |
| Saturated Fat | Sat fat | Insoluble fiber | Insol fiber |
| Monounsaturated fat | Monounsat fat | Sugar alcohol | Sugar alc |
| Polyunsaturated | Polyunsat fat | Other carbohydrate | Other carb |

# Hemp and Kratom Product Labeling - Dietary Supplements

**FROM THE FDA'S DIETARY SUPPLEMENTS LABELING GUIDE:**

**https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory- information/dietary-supplement-labeling-guide**

**How are dietary supplements defined?**

Dietary supplements are defined, in part, as products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients:

- A vitamin.
- A mineral.
- An herb or other botanical.
- An amino acid.
- A dietary substance for use by man to supplement the diet by increasing the total dietary intake.
- A concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above.

Further, dietary supplements are products intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal or the diet, and are labeled as dietary supplements. The complete statutory definition is found in section 201(ff) of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321).

**What label statements are required on the containers and packages of dietary supplements?**

Five statements are required: 1) the statement of identity (name of the dietary supplement), 2) the net quantity of contents statement (amount of the dietary supplement), 3) the nutrition labeling, 4) the ingredient list, and 5) the name and place of business of the manufacturer, packer, or distributor. 21 CFR 101.3(a), 21 CFR 101.105(a), 21 CFR 101.36, 21 CFR 101.4(a)(1), and 21 CFR 101.5.

**Where do I place the required label statements?**

You must place all required label statements either on the front label panel (the principal display panel) or on the information panel (usually the label panel immediately to the right of the principal display panel, as seen by the consumer when facing the product), unless otherwise specified by regulation (i.e., exemptions). 21 CFR 101.2(b) and (d), 21 CFR 101.9(j)(13) and (j)(17), 21 CFR 101.36(g), (i)(2) and (i)(5).

**What label statements must I place on the principal display panel?**

You must place the statement of identity and the net quantity of contents statement on the principal display panel. Where packages bear alternate principal display panels, you must place this information on each alternate principal display panel 21 CFR 101.1, 21 CFR 101.3(a) and 21 CFR 101.105(a).

**How do I locate the principal display panel?**

The principal display panel of the label is the portion of the package that is most likely to be seen by the consumer at the time of display for retail purchase. Many containers are designed with two or more different surfaces that are suitable for use as the principal display panel. These are alternate principal display panels. 21 CFR 101.1.

**What label statements must I place on the information panel?**

You must place the "Supplement Facts" panel, the ingredient list, and the name and place of business of the manufacturer, packer, or distributor on the information panel if such information does not appear on the principal display panel, except that if space is insufficient, you may use the special provisions on

the “Supplement Facts” panel in 21 CFR 101.36(i)(2)(iii) and (i)(5). See questions 46 and 56 in Chapter IV for more details. 21 CFR 101.2(b) and (d), 101.36(i)(2)(iii) and (i)(5), 101.5, 101.9(j)(13)(i)(A) and (j)(17).

**Where is the information panel?**

The information panel is located immediately to the right of the principal display panel as the product is displayed to the consumer. If this panel is not usable, due to package design and construction (e.g. folded flaps), the panel immediately contiguous and to the right of this part may be used for the information panel. The information panel may be any adjacent panel when the top of a container is the principal display panel. 21 CFR 101.2(a).

**What name and address must I list on the label of my product?**

You must list the street address if it is not listed in a current city directory or telephone book, the city or town, the state, and zip code. You may list the address of the principal place of business in lieu of the actual address. 21 CFR 101.5.

**May I place intervening material on the information panel?**

No. You may not place intervening material, which is defined as label information that is not required (e.g., UPC bar code), between label information that is required on the information panel. 21 CFR 101.2(e).

**What type size, prominence and conspicuousness am I required to use on the principal display panel and the information panel?**

You are required to use a print or type size that is prominent, conspicuous and easy to read. The letters must be at least one-sixteenth (1/16) inch in height based on the lower case letter “o,” and not be more than three times as high as they are wide, unless you petition for an exemption in accordance with 21 CFR 101.2(f). The lettering must contrast sufficiently (it does not need to be black and white) with the background so as to be easy to read. See Chapter IV for the type size requirements for the nutrition label. 21 CFR 101.2(c) and (f), 21 CFR 101.15, and 21 CFR 101.105(h).

**Do I need to specify the country of origin if my product, or the ingredients in my product, is not from the United States?**

Yes. Unless excepted by law, the Tariff Act requires that every article of foreign origin (or its container) imported into the United States conspicuously indicate the English name of the country of origin of the article. Section 304, Tariff Act of 1930, as amended (19 U.S.C. 304).

**Who regulates the statement “Made in the U. S. A.”?**

FDA does not have regulatory authority over such statements. The U.S. Customs Service regulates country of origin marking (i.e., “Made in the U.S.A.”) as authorized by the Tariff Act of 1930. Their website is www.customs.ustreas.gov.

**How do I obtain a UPC bar code?**

The UPC bar code may be obtained from the Uniform Code Council. Their website is www.uc- council. org. Click on the button that says “I Need a UPC Bar Code.”

**Must expiration dating be included on the label of dietary supplements?**

No. However, a firm may include this information if it is supported by valid data demonstrating that it is not false or misleading.

**What is the statement of identity for a dietary supplement and where must I place it?**

The statement of identity for a dietary supplement is the name that appears on the label of the dietary supplement. As a general matter, the statement of identity of a food (including dietary supplements) is the name specified by federal law or regulation, or, if no such name is specified, the common or usual name of the food. If the food has no common or usual name and the nature of the food is not obvious, the statement of identity must be an appropriately descriptive term. In the case of dietary supplements,

both the Federal Food, Drug, and Cosmetic Act and FDA's regulations specify that the statement of identity must include the term "dietary supplement," except that the word "dietary" may be replaced with a description of the type of dietary ingredient(s) in the product (e.g., "herbal supplement") or the names of one or more dietary ingredients in the product (e.g., "bee pollen supplement"). You must place the statement of identity on the principal display panel of the dietary supplement and on any alternate principal display panels. Brand names are not considered to be statements of identity and should not be unduly prominent compared to the statement of identity. 21 U.S.C. 321(ff)(2)(C), 21 U.S.C. 343(s)(2)(B), 21 CFR 101.1 and 21 CFR 101.3.

**How am I required to identify a dietary supplement?**

You must identify a dietary supplement by using the term "dietary supplement" in the statement of identity, except that you may delete the word "dietary" and replace it with the name of the dietary ingredient(s) in the product (e.g., "calcium supplement") or an appropriately descriptive term indicating the type of dietary ingredient(s) in your dietary supplement product (e.g., "herbal supplement with vitamins"). 21 U.S.C. 321(ff)(2)(C), 21 U.S.C. 343(s)(2)(B) and 21 CFR 101.3(g).

**Can the term "dietary supplement" by itself be considered the statement of identity?**

Yes. This term describes the basic nature of a dietary supplement and therefore is an "appropriately descriptive term" that can be used as the product's statement of identity. The statement of identity for a dietary supplement may therefore consist simply of the term "dietary supplement," or "dietary supplement" may be part of a longer statement of identity (e.g., "cod liver oil liquid dietary supplement"). In either case, the word ''dietary'' may be deleted and replaced by another appropriately descriptive term identifying the contents of the product, such as "calcium supplement," "herbal supplement", or "herbal supplement with vitamins." 21 CFR 101.3(g).

**Should I make the statement of identity stand out?**

Yes. You must make the statement of identity one of the most important features on the principal display panel. To do this, you must use bold type and a type size reasonably related to the most prominent printed matter on the front panel of your label. 21 CFR 101.3(d).

**How should I place the statement of identity on the principal display panel?**

You must place the statement of identity of your dietary supplement product in lines generally parallel to the base of the package. 21 CFR 101.3(d).

**What is the net quantity of contents statement for a dietary supplement?**

The net quantity of contents statement for a dietary supplement is the statement that informs consumers of the amount of dietary supplement that is in the container or package. 21 CFR 101.105(a).

**Where must I locate the net quantity of contents statement on my label?**

You must locate the net quantity of contents statement on your product label as a distinct item in the bottom 30 percent of the principal display panel, in lines generally parallel with the base of the container. If the principal display panel of your product is 5 square inches or less, the requirement for placement within the bottom 30 percent does not apply when the declaration of net quantity of contents meets the other requirements of 21 CFR 101. 21 CFR 101.105(f).

**How must I express the net quantity of contents statement on my label?**

You must express the net quantity of contents statement in either weight, measure, numerical count or a combination of numerical count and weight or measure. When you express this quantity as a weight or measure, you must specify both metric (grams, kilograms, milliliters, or liters) and U.S. Customary System (ounces, pounds, or fluid ounces) terms. Public Law 102-329, August 3, 1992 and 21 CFR 101.105.

**Why must I calculate the area of the principal display panel?**

You must calculate the area of the principal display panel (calculated in square inches or square centimeters) to determine the minimum type size that is permitted for the net quantity of contents statement. 21 CFR 101.1.

**How do I calculate the area of the principal display panel?**

You may calculate the area of the principal display panel for rectangular or square shaped packages by multiplying the height by the width (both in inches or both in centimeters), and for cylindrical shaped packages by multiplying 40% of the circumference by the height. For example, a rectangular package that is 8 inches high and 6 inches wide would have a principal display panel of 48 square inches. A cylindrical package having a circumference of 10 inches and a height of 2 inches would have a principal display panel of 8 square inches. 21 CFR 101.1.

**Am I required to place the net quantity of contents statement conspicuously and prominently on my product labels?**

Yes. You are required to use a print style that is prominent, conspicuous, and easy to read, with letters not more than three times as high as wide. Use letters that contrast sufficiently with the background. 21 CFR 101.15 and 21 CFR 101.105(h).

**What is the minimum type size that I can use for the net quantity of contents statements?**

The smallest type size permitted for the net quantity of contents statement is based on the size of the principal display panel. You may determine the height of the type by measuring the height of upper case letters, when only upper case letters are used, or the height of a lower case letter "o," or its equivalent, when mixed upper and lower case letters are used. The table below sets out the minimum type size in inches (in.), with metric equivalents (millimeters (mm) and centimeters (cm)) in parentheses. 21 CFR 101.105(h) and (i).

| Minimum Type Size | Area of Principal Display Panel |
|---|---|
| 1/16 in. (1.6 mm) | 5 sq. in. (32 sq. cm.) or less |
| 1/8 in. (3.2 mm) | More than 5 sq. in. (32 sq. cm.) but not more than 25 sq. in. (161 sq. cm.) |
| 3/16 in. (4.8 mm) | More than 25 sq. in. (161 sq. cm.) but not more than 100 sq. in. (645 sq. cm.) |
| 1/4 in. (6.4 mm) | More than 100 sq. in. (645 sq. cm.) but not more than 400 sq. in. (2580 sq. cm.) |
| 1/2 in. (12.7 mm) | Over 400 sq. in. (2580 sq. cm.) |

**What must I include in a weight-based net quantity of contents statement?**

You must include only the quantity of the dietary supplement in a container, and not the weight of the container, wrappers and packing materials, except that in the case of dietary supplements packed in containers designed to deliver the dietary supplement under pressure, the propellant is included in the net quantity declaration. 21 CFR 101.105(g).

**What must I include in a numerical count-based net quantity statement?**

You must include the number of units in a container, e.g. "100 tablets." 21 CFR 101.105(a).

**May I use qualifying phrases in the net quantity of contents statement?**

No. You may not use qualifying phrases that qualify a unit or weight, measure, or count (such as "jumbo quart" and "full gallon") in the net quantity of contents statement because they tend to exaggerate the amount of the dietary supplement in the container. 21 CFR 101.105(f).

**What is the nutrition label for a dietary supplement called?**

The nutrition label for a dietary supplement is called a "Supplement Facts" panel (see sample labels at the end of this chapter). 21 CFR 101.36(b)(1)(i).

**How does "Supplement Facts" differ from "nutrition facts?"**

The major differences between "Supplement Facts" panel and "Nutrition Facts" panel are as follows:

1. You must list dietary ingredients without RDIs or DRVs in the "Supplement Facts" panel for dietary supplements. You are not permitted to list these ingredients in the "Nutrition Facts" panel for foods.

2. You may list the source of a dietary ingredient in the "Supplement Facts" panel for dietary supplements. You cannot list the source of a dietary ingredient in the "Nutrition Facts" panel for foods.

3. You are not required to list the source of a dietary ingredient in the ingredient statement for dietary supplements if it is listed in the "Supplement Facts" panel.

4. You must include the part of the plant from which a dietary ingredient is derived in the "Supplement Facts" panel for dietary supplements. You are not permitted to list the part of a plant in the "Nutrition Facts" panel for foods.

5. You are not permitted to list "zero" amounts of nutrients in the "Supplement Facts" panel for dietary supplements. You are required to list "zero" amounts of nutrients in the "Nutrition Facts" panel for food. 21 CFR 101.36(b)(3) and (b)(2)(i), 21 CFR 101.4(h), 21 CFR 101.36(d) and (d)(1), and 21 CFR 101.9.

**What information must I list in the "Supplement Facts" panel?**

You must list the names and quantities of dietary ingredients present in your product, the "Serving Size" and the "Servings Per Container." However, the listing of "Servings Per Container" is not required when it is the same information as in the net quantity of contents statement. For example, when the net quantity of contents statement is 100 tablets and the "Serving Size" is one tablet, the "Serving Per Container" also would be 100 tablets and would not need to be listed. 21 CFR 101.36(b).

**SERVING SIZE**

**What is the serving size for a dietary supplement?**

One serving of a dietary supplement equals the maximum amount recommended, as appropriate, on the label for consumption per eating occasion, or in the absence of recommendations, 1 unit (e.g., tablet, capsule, packet, teaspoonful, etc.). For example, if the directions on your label say to take 1-3 tablets with breakfast, the serving size would be 3 tablets. 21 CFR 101.12(b) Table 2 in the Miscellaneous Category.

**May I use flexibility in the wording for "Serving Size?"**

No. You must use the term "Serving Size." 21 CFR 101.36(b)(1).

**What are the circumstances in which my dietary supplement products would be exempt from the nutrition labeling requirements?**

Your dietary supplement product is not required to have a "Supplement Facts" panel if:

A. Your firm is a small business that has not more than $50,000 gross sales made or business done in sales of food to consumers or not more than $500,000 per year from total sales in accordance with 21 CFR 101.36(h)(1);

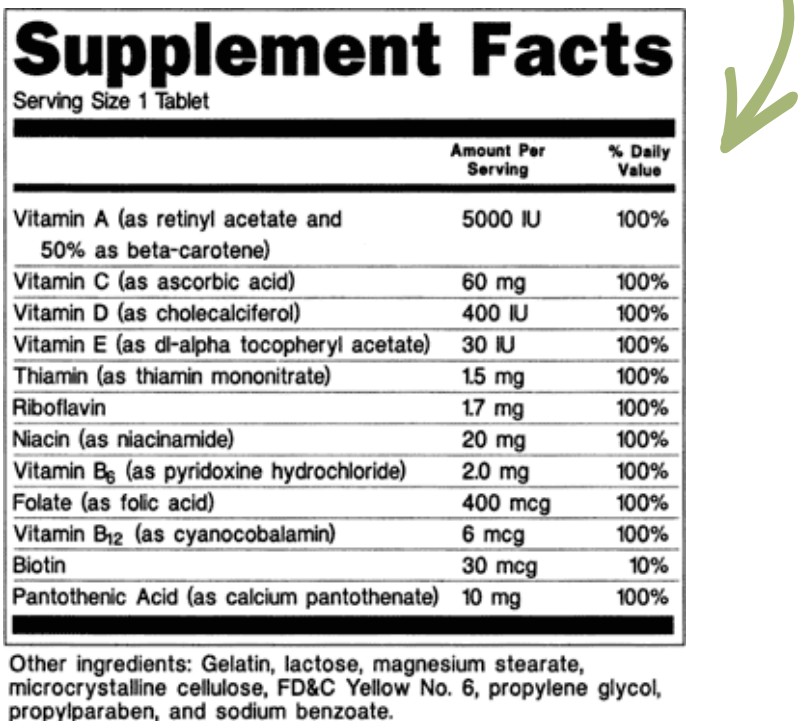
B. You sell less than 100,000 units of the product annually, your firm has fewer than 100 full-time equivalent employees in accordance with 21 CFR 101.36(h)(2) and you file an annual notification with FDA as specified in 21 CFR 101.9(j)(18)(iv); or

C. You ship the product in bulk form, do not distribute it to consumers in such form, and you supply it for use in the manufacture of other dietary supplements in accordance with 21 CFR 101.36(h)(3).

The two exemptions for small businesses and low-volume products (a. and b. above) are available to you only if your products' labels bear no claims or other nutrition information. 21 CFR 101.36(h)(1) - (3).

**Does FDA have sample labels for dietary supplements?**

Yes. See sample labels below.



**Supplement Facts**

Serving Size 1 Tablet

| | Amount Per Serving | % Daily Value |
|---|---|---|
| Vitamin A (as retinyl acetate and 50% as beta-carotene) | 5000 IU | 100% |
| Vitamin C (as ascorbic acid) | 60 mg | 100% |
| Vitamin D (as cholecalciferol) | 400 IU | 100% |
| Vitamin E (as dl-alpha tocopheryl acetate) | 30 IU | 100% |
| Thiamin (as thiamin mononitrate) | 1.5 mg | 100% |
| Riboflavin | 1.7 mg | 100% |
| Niacin (as niacinamide) | 20 mg | 100% |
| Vitamin $B_6$ (as pyridoxine hydrochloride) | 2.0 mg | 100% |
| Folate (as folic acid) | 400 mcg | 100% |
| Vitamin $B_{12}$ (as cyanocobalamin) | 6 mcg | 100% |
| Biotin | 30 mcg | 10% |
| Pantothenic Acid (as calcium pantothenate) | 10 mg | 100% |

Other ingredients: Gelatin, lactose, magnesium stearate, microcrystalline cellulose, FD&C Yellow No. 6, propylene glycol, propylparaben, and sodium benzoate.

**What is an "ingredient"?**

The Dietary Supplement Health and Education Act uses the term "ingredient" to refer to the compounds used in the manufacture of a dietary supplement. For instance, when calcium carbonate is used to provide calcium, calcium carbonate is an "ingredient" and calcium is a "dietary ingredient." The term "ingredient" also refers to substances such as binders, colors, excipients, fillers, flavors, and sweeteners. Public Law 103-417, 60 Federal Register 67194 at 67199 (December 28, 1995).

**What is unique about the ingredient labeling of dietary supplements?**

Ingredients that are sources of dietary ingredients may be listed within the "Supplement Facts" panel, e.g., "Calcium (as calcium carbonate)." When ingredients are listed in this way, they do not have to be listed again in the ingredient statement (also called an ingredient list). 21 CFR 101.36(d).

**Do I need an ingredient statement when all of my ingredients are listed in the "Supplement Facts" panel?**

No. If you place all source ingredients in the "Supplement Facts" panel and you have no other ingredients, such as excipients or fillers, you do not need an ingredient statement. 21 CFR 101.4(a)(1).

**How must I identify the ingredient list?**

You must precede the ingredient list by the word "Ingredients," except that you must use the words "Other Ingredients" when you have identified some ingredients (i.e., as sources) within the nutrition label. 21 CFR 101.4(g).

**Where must I place the ingredient list on the label?**

When present, you must place the ingredient list on dietary supplements immediately below the nutrition label, or if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label. 21 CFR 101.4(g).

**What type size must I use for the ingredient list?**

You must display this information prominently and conspicuously, but in no case may the types size be less that 1/16 inch in height as measured by the lower case "o", or its equivalent, in accordance with 21 CFR 101.105(h)(2). 21 CFR 101.2(c), 21 CFR 101.15, and 21 CFR 101.105(h)(1) and (2).

**Must I list the ingredients in a specified order?**

Yes. You must list the ingredients in descending order of predominance by weight. This means that the ingredient that weighs the most is first and the ingredient that weighs the least is last. 21 CFR 101.4(a).

**How must I declare spices, natural flavors, or artificial flavors?**

You must declare these ingredients in ingredient lists by using either specific common or usual names or by using the declarations "spice," "natural flavor" or "artificial flavor," or any combination thereof. 21 CFR 101.22(h)(1) and 21 CFR 101.4(a)(1).

**Can I indicate that a spice is also a coloring?**

Yes. Paprika, turmeric, saffron and other spices that are also colorings, may be declared either by name or the term "spice and coloring." For example, paprika may be listed as "paprika" or as "spice and coloring." 21 CFR 101.22(a)(2).

**How must I declare artificial colors?**

It depends on whether or not the artificial color is certified. List a certified color by its specific or abbreviated name, e.g., "FD&C Red No. 40" or "Red 40."

A color that is not certified may be listed as an "Artificial Color," "Artificial Color Added," "Color Added, "or by its specific common or usual name. 21 CFR 101.22(k)(1) and (k)(2).

**May I use "and/or" labeling for fats and oils?**

Yes. When a blend of fats and/or oils is not the predominant ingredient of your product and you vary the makeup of the blend you may use "and/or" labeling or language such as:

INGREDIENTS:...vegetable oil shortening (contains one or more of the following: cottonseed oil, palm oil, soybean oil)." 21 CFR 101.4(b)(14).

**Do I need to list water?**

Yes. You must identify the added water in the list of ingredients in descending order of predominance by weight. For example:

"Ingredients: Cod liver oil, gelatin, water, and glycerin" 21 CFR 101.4(a) and (c) and 21 CFR 101.36(e)(10)(iv).

**How do I list a chemical preservative?**

You must list the common or usual name of the preservative followed by a description that explains its function e.g., "preservative," "to retard spoilage," "a mold inhibitor," "to help protect flavor," or "to promote color retention." 21 CFR 101.22(j).

**What is a new dietary ingredient?**

A new dietary ingredient is a dietary ingredient that was not marketed in the United States before October 15, 1994, and does not include any dietary ingredient which was marketed in the United States before October 15, 1994. 21 U.S.C. 350b(c).

**Is premarket notification required for new dietary ingredients?**

Yes. The manufacturer or distributor of a new dietary ingredient or of a dietary supplement that contains a new dietary ingredient must submit a notification to FDA at least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains the new dietary ingredient. 21 U.S.C. 305b(a).

**Are there regulations about premarket notification for new dietary ingredients?**

Yes. FDA has issued regulations on premarket notification for new dietary ingredients in 21 CFR 190.6.

21 CFR 190.6.

**Where do I submit my new dietary ingredient premarket notification?**

You must send the premarket notification to the Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-800), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Parkway, College Park, MD 20740-3835. You must submit the original and two copies of the document. 21 CFR 190.6(a).

**What information must I include in my premarket notification for a new dietary ingredient?**

You must submit the following information:

- The name and complete address of the manufacturer or distributor of a dietary supplement that contains the new dietary ingredient, or of the new dietary ingredient;
- The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or otherbotanical;
- A description of the dietary supplement or dietary supplements that will contain the new dietary ingredient including:
    - the level of the new dietary ingredient in the dietary supplement; and
    - the conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;
- The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which you have concluded that the new dietary supplement will reasonably be expected to be safe. You must submit reprints or photostatic copies of published information that you reference in support of the notification material. You must submit an accurate and complete English translation of any material you submit in a foreign language; and
- Your signature, or that of a person you designate. 21 CFR 190.6(b).

**What does FDA do with my premarket notification for a new dietary ingredient?**

FDA will acknowledge its receipt of a notification made under section 413 of the act and will notify you of the date of receipt of such a notification. The date that the agency receives the notification is the filing date for the notification. For 75 days after the filing date, you must not introduce, or deliver for introduction, into interstate commerce any dietary supplement that contains the new dietary ingredient. 21 CFR 190.6(c).

**What happens if I submit additional information?**

If you provide additional information, including responses you make to inquiries from the agency, in support of your new dietary ingredient notification, the agency will review the information to determine whether it is substantive. If the agency determines that the new submission is a substantive

amendment, the agency will designate the date of its receipt by FDA as the new filing date. FDA will acknowledge receipt of the additional information and, when applicable, will notify you of the new filing date, which restarts the 75-day period. 21 CFR 190.6(d).

**Will FDA maintain the confidentiality of my premarket notification for a new dietary ingredient?**

FDA will not disclose the existence of, or the information contained in, a new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, FDA will place all information in the notification on public display, except for any information that is trade secret or otherwise confidential commercial information. 21 CFR 190.6(e).

**Is no response from FDA to a new dietary ingredient premarket notification an indication that the FDA finds that the product is safe and not adulterated?**

No. Failure of the agency to respond to your notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act (21 U.S.C. 342). 21 CFR 190.6(f).

**Are there special labeling requirements for iron-containing dietary supplements?**

Yes. You must label any dietary supplement in solid oral dosage form (e.g., tablets or capsules) that contains iron or iron salts for use as an iron source with a specific warning statement. 21 CFR 101.17(e).

**What is the text of the warning statement?**

The text of the warning statement is as follows:

**WARNING:** Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately. 21 CFR 101.17(e)(1).

**May I deviate from the specified text of the warning statement?**

No. You may not make deviations from the specified test. 21 CFR 101.17(e)(1).

**Where must I locate the warning statement?**

You must place the warning statement prominently and conspicuously on the information panel of the product's immediate container. You must set the warning statement off in a box using hairlines. You must also place it on any labeling that contains warnings. If the immediate container has an outer package, you must also place the warning statement on the outer package. 21 CFR 101.17(e)(2) through(5).

**Are there packaging requirements for iron-containing dietary supplements?**

No. FDA revoked its regulations on "Packaging of iron-containing dietary supplements" (21 CFR 111.5) on October 17, 2003, in response to a U.S. federal appeals court decision that FDA lacked the authority to require unit-dose packaging of dietary supplements for the purpose of poison prevention. 68 Federal Register 59714; October 17, 2003.

**Is there a limit on the folic acid content in dietary supplements?**

No. FDA does not specify any limit on the folic acid content that may be contained in dietary supplements.

**Who regulates whether I can make a claim indicating that my product is organic?**

Organic claims are regulated by the U.S. Department of Agriculture under the National Organic Program. **Their website is www.usda.gov.**

# Hemp and Kratom Product Labeling - Cosmetics

Cosmetics marketed in the United States, whether manufactured here or imported from abroad, must be in compliance with the provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act), Fair Packaging and Labeling Act External Link Disclaimer (FP&L Act), and the regulations published under the authority of these laws.

The regulations published by the Food and Drug Administration (FDA) are all codified in Title 21, Code of Federal Regulations (21 CFR). The regulations related to cosmetics are stated at 21 CFR, parts 700 to 740 (21 CFR 700 to 740). The color additive regulations that apply to cosmetics are found at 21 CFR 73, 74, 81 and 82.

**Legal Definition of "Cosmetics"**

The FD&C Act defines cosmetics as articles intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance

without affecting the body's structure or functions. Included in this definition are products such as skin creams, lotions, perfumes, lipsticks, fingernail polishes, eye and facial make-up preparations, shampoos, permanent waves, hair colors, toothpastes, deodorants, and any material intended for use as a component of a cosmetic product. Soap products consisting primarily of an alkali salt of fatty acid and making no label claim other than cleansing of the human body are not considered cosmetics under the law.

**Cosmetics That Are Also Drugs**

Products that are cosmetics but are also intended to treat or prevent disease, or affect the structure or functions of the human body, are considered also drugs and must comply with both the drug and cosmetic provisions of the law. Examples of products which are drugs as well as cosmetics are anticaries toothpastes (e.g., "fluoride" toothpastes), suntanning preparations intended to protect against sunburn, antiperspirants that are also deodorants, and antidandruff shampoos.

Most currently marketed cosmetics which are also drugs are over-the-counter drugs. Several are new drugs for which safety and effectiveness had to be proved to the agency before they could be marketed. A new drug is a drug which is not generally recognized by experts as safe and effective under the conditions of intended use or which has become so recognized but has not been used to a material extent or for a material time under such conditions.

The regulatory requirements for drugs are more extensive than the requirements applicable to cosmetics. For example, the FD&C Act requires that drug manufacturers register every year with the FDA and update their lists of all manufactured drugs twice annually. Additionally, drugs must be manufactured in accordance with current good manufacturing practice regulations as codified at 21 CFR 210 and 211.

**Adulterated or Misbranded Cosmetics**

The FD&C Act prohibits the distribution of cosmetics which are adulterated or misbranded. A cosmetic is considered adulterated if it contains a substance which may make the product harmful to consumers under customary conditions of use; if it contains a filthy, putrid, or decomposed substance; if it is manufactured or held under insanitary conditions whereby it may have become contaminated with filth, or may have become harmful to consumers; or if it is not a hair dye and it contains a non-permitted color additive. Coal-tar hair dyes bearing on the label the caution statement prescribed by law and that give "patch-test" instructions are exempted from the adulteration provision even if they are irritating to the skin or are otherwise harmful to the human body. Eyelash and eyebrow dyes are not included in this exemption. All dyes used in eyelash and eyebrow dye products must be approved by the FDA for such use.

A cosmetic is misbranded if its labeling is false or misleading, if it does not bear the required labeling information, or if the container is made or filled in a deceptive manner.

**Cosmetic Labeling**

The cosmetics distributed in the United States must comply with the labeling regulations published by the FDA under the authority of the FD&C Act and the FP&L Act. Labeling means all labels and other written, printed or graphic matter on or accompanying a product. The label statements required under the authority of the FD&C Act must appear on the inside as well as any outside container or wrapper. FP&L Act requirements, e.g., ingredient labeling and statement of the net quantity of contents on the principal display panel, only apply to the label of the outer container. The labeling requirements are codified at 21 CFR 701 and 740. Cosmetics bearing false or misleading label statements or otherwise not labeled in accordance with these requirements may be considered misbranded and may be subject to regulatory action.

The principal display panel, i.e., the part of the label most likely displayed or examined under customary conditions of display for sale (21 CFR 701.10), must state the name of the product, identify by descriptive name or illustration the nature or use of the product, and bear an accurate statement of the net quantity of contents of the cosmetic in the package in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure. The declaration must be distinct, placed in the bottom area of the panel in line generally parallel to the base on which the package rests, and in a type size commensurate with the size of the container as prescribed by regulation. The net quantity of contents statement of a solid, semisolid or viscous cosmetic must be in terms of the avoirdupois pound and ounce, and a statement of liquid measure must be in terms of the U.S. gallon of 231 cubic inches and the quart, pint, and fluid ounce subdivisions thereof. If the net quantity of contents is one pound or one pint or more, it must be expressed in ounces, followed in parenthesis () by a declaration of the largest whole units (i.e., pounds and ounces or quarts and pints and ounces). The net quantity of contents may additionally be stated in terms of the metric system of weights or measures.

The name and place of business of the firm marketing the product must be stated on an information panel of the label (21 CFR 701.12). The address must state the street address, city, state, and zip code. If a firm is listed in a current city or telephone directory, the street address may be omitted. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for ....." or "Distributed by " or similar, appropriate wording.

The Tariff Act of 1930 requires that all imported articles state on the label the English name of the country of origin.

**Declaration of Ingredients**

Cosmetics produced or distributed for retail sale to consumers for their personal care are required to bear an ingredient declaration (21 CFR 701.3). Cosmetics not customarily distributed for retail sale, e.g., hair preparations or make-up products used by professionals on customers at their establishments and skin cleansing or emollient creams used by persons at their places of work, are exempt from this requirement provided these products are not also sold to consumers at professional establishments or workplaces for their consumption at home.

The ingredient declaration must be conspicuous so that it is likely to be read at the time of purchase. It may appear on any information panel of the package, i.e., the folding carton, box wrapping if the immediate container is so packaged, and may also appear on a firmly affixed tag, tape or card. The letters must not be less than 1/16 of an inch in height (21 CFR 701.3 (b)). If the total package surface available to bear labeling is less than 12 square inches, the letters must not be less than 1/32 of an inch in height (21 CFR 701.3(p)). Off-package ingredient labeling is permitted if the cosmetic is held in tightly compartmented trays or racks, it is not enclosed in a folding carton, and the package surface area is less than 12 square inches. (21 CFR 701.3(i)).

The ingredients must be declared in descending order of predominance. Color additives (21 CFR 701.3(f)(3)) and ingredients present at one percent or less (21 CFR 701.3(f)(2)) may be declared without regard for predominance. The ingredients must be identified by the names established or adopted by regulation (21 CFR 701.3(c)); those accepted by the FDA as exempt from public disclosure may be stated as "and other ingredients". (21 CFR 701.3(a)).

Cosmetics which are also drugs must first identify the drug ingredient(s) as "active ingredient(s)" before listing the cosmetic ingredients. (21 CFR 701.3(d)).

All label statements required by regulation must be in the English language and must be placed on the label or labeling with such prominence and conspicuousness that they are readily noticed and understood by consumers under customary conditions of purchase. (21 CFR 701.2).

**Label Warnings**

Cosmetics which may be hazardous to consumers when misused must bear appropriate label warnings and adequate directions for safe use. The statements must be prominent and conspicuous. Some cosmetics must bear label warnings or cautions prescribed by regulation (21 CFR 740). Cosmetics in self- pressurized containers (aerosol products), feminine deodorant sprays, and children's bubble bath products are examples of products requiring such statements.

Although the FD&C Act does not require that cosmetic manufacturers or marketers test their products for safety, the FDA strongly urges cosmetic manufacturers to conduct whatever toxicological or other tests are appropriate to substantiate the safety of their cosmetics. If the safety of a cosmetic is not adequately substantiated, the product may be considered misbranded and may be subject to regulatory action unless the label bears the following statement: Warning--The safety of this product has not been determined. Sec. 21 CFR 740.10.

**Tamper-Resistant Packaging**

Liquid oral hygiene products (e.g., mouthwashes, fresheners) and all cosmetic vaginal products (e.g., douches, tablets) must be packaged in tamper-resistant packages when sold at retail. A package is considered tamper resistant if it has an indicator or barrier to entry (e.g., shrink or tape seal, sealed carton, tube or pouch, aerosol container) which, if breached or missing, alerts a consumer that tampering has occurred. The indicator must be distinctive by design (breakable cap, blister) or appearance (logo, vignette, other illustration) to preclude substitution. The tamper-resistant feature may involve the immediate or outer container or both. The package must also bear a prominently placed statement alerting the consumer to the tamper-resistant feature. This statement must remain unaffected if the tamper-resistant feature is breached or missing. Sec. 21 CFR 700.25.

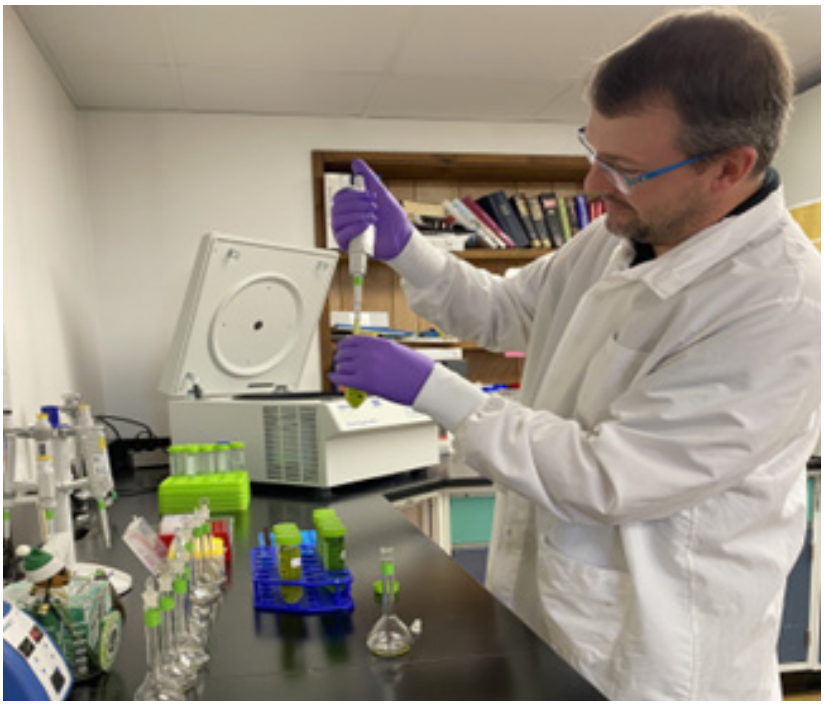
## Inspection and Testing

The Department will conduct random inspections of hemp and kratom products distributed or made available for sale in the state.

The Department will periodically inspect, sample and analyze hemp and kratom products within the state for compliance with an registration, labeling requirements, and product safety.

The Department may conduct inspection of hemp and kratom products distributed or available for distribution for any reason that the Department deems necessary.

Samples taken by the Department shall be the official samples.



## Handling and Transport

It is lawful in West Virginia to transport and possess kratom, CBD and THC products, so long as the total THC content does not exceed 0.3 percent and the 7-hydroxymitragynine is lower than 0.2 percent.

Hemp and kratom products may be legally transported across state lines and exported to foreign countries in a manner that is consistent with federal law and laws of respective foreign countries.

For time and temperature controlled products for human consumption, sellers must meet FDA guidance for maintaining safe handling, storage, and preservation of the product.

## Enforcement Actions, Violations and Related Penalties

**Enforcement actions on unregistered sellers, distributors, and product manufacturers:**

If the seller, distributor, or a manufacturer does not renew its registration annually, the Commissioner is authorized to take enforcement actions against the seller or manufacturer as set forth in this section.

**Upon the first offense:**

- The seller, distributor, or product manufacturer will be notified in writing that they must register with the Department
- The seller, distributor, or product manufacturer will be given 14 days to register with the Department; and
- If the seller, distributor, or product manufacturer does not register with the Department in the allotted time, their hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.

**Upon the second offense within a five-year period:**

- The seller, distributor, or product manufacturer will be notified in writing that they must register with the Department;
- The seller, distributor, or product manufacturer will be given 14 days to register with the Department, and will then be subject to the regular registration fee in addition to a penalty;
- The seller, distributor, or product manufacturer will be required to pay a penalty of $500.00; and
- If the seller, distributor, or product manufacturer does not register with the Department in the allotted time, the hemp products shall be embargoed and removed from the shelves in accordance with section 12 of 61CSR30.

**Upon a third offense in a five-year period:**

- The seller, distributor, or product manufacturer will be notified in writing that they must register with the Department;
- The product shall be embargoed and removed from shelves in accordance with section 12 of 61CSR30.
- The seller, distributor, or product manufacturer shall be required to pay a penalty of $1,000.00 and
- The permit shall be suspended for one year. An informal hearing can be requested to consider reinstatement of a suspended permit.
- Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment, distributor, or manufacturer.

**Enforcement actions on unregistered sellers, manufacturers, and products.**

If the seller, distributor, or a manufacturer does not renew its registration annually, the Commissioner is authorized to take enforcement actions against the seller, distributor, or manufacturer as set forth in this section.

**Upon the first offense:**

- The seller, distributor, or product manufacturer will be notified in writing that they must register with the Department; and
- The seller, distributor, or product manufacturer will be given 15 business days from date of attempted delivery of notice to register with the Department.
- Upon the second offense (first violation) within a one-year period:
- The distributor, seller and/or product manufacturer will be notified in writing that they must register with the Department;
- The distributor, seller and/or product manufacturer will be required to pay a fine of $1,000.00 and The hemp products shall be embargoed and removed from the shelves in accordance with section 12 of this rule.
- Any person in violation of this section shall be guilty of a crime and subject to criminal penalties in accordance with section 19E-12E(m)(o)

**Upon a third offense (second violation) in a one-year period:**

- The distributor, seller and/or product manufacturer will be notified in writing that they must register with the Department;
- The product shall be embargoed and removed from shelves in accordance with section 12 of this rule;
- The distributor, seller and/or product manufacturer shall be required to pay a penalty of $5,000; and
- For unregistered sellers and/or distributors, the eligibility to obtain a permit to sell hemp and kratom products shall be suspended for one year. The permit holder shall have the right to request an optional informal hearing.
- For unregistered products, the ability to obtain a product permit shall be suspended for one year. The product permit holder shall have the right to request an optional hearing.
- Embargoes and offenses shall be specific to the individual product and not the entire manufacturer's line of products.
- Any person in violation of this section shall be guilty of a crime and subject to criminal penalties in accordance with section 19E-12E(m)(o)
- Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment, distributor, or manufacturer.

**Enforcement actions on products violations and related penalties.**

The Commissioner may assess a violation of West Virginia Code §19-12E-7.

Violations shall be broken into classes, dependent on the severity. Violations are classified as follows:

**Class I violations are flagrant violations and include, but are not limited to:**

Hemp and kratom products that are unsafe or adulterated or show cause for immediate human or animal health concern;

Hemp products that contain more than the THC content authorized by law.;

Products sampled by the laboratory are subject to the determination of flagrant violation by the commissioner

Third offense registration violations as defined in subsection 10.4 11.4 of this rule.; and Improper labeling, as defined in subdivision 8.9.b and subsection 8.14 of this rule.

**Class II violations are violations in which the person acted in a faulty or careless manner and include, but are not limited to:**

Falsification of information on an application;

No serving size and frequency of use listed on labeling; and

Failure of the product to meet label claims.

**Class III violations are negligent violations and include but are not limited to:**

Improper labeling; and Misbranding.

Class III (Negligent) Violations.

**Upon the first Class III violation being committed by a manufacturer:**

The Commissioner shall send a written "First Notice" to the registrant. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 et. seq. of this rule and the enforcement policy established by this section of the rule has been violated.

The manufacturer shall be assessed a $200.00 penalty for the Class III violation.

The manufacturer shall be given 30 days to fix the Class III violation and must provide evidence to the Department that the violation has been corrected.

If a second Class III violation has been committed on the same products within a one year period, the Commissioner shall send a written "Second Notice" to the registrant. The registrant must develop a written plan to correct the violation(s) and implement it within 10 business days after the Second Notice has been sent. An additional $500.00 penalty will be assessed for the second Class III violation of a product.

If a third Class III violation has been committed on the same product within a oneyear period, the Commissioner will issue an immediate "Suspension of Permit."

The "Suspension of Permit" order will give the reason for the order and the length of time the Suspension of Permit order will be in effect.

The suspension of permit order shall state the time that the suspension will be effective and give the reason for the suspension. In the case of a summary suspension, the Commissioner may give the manufacturer an opportunity to request an informal hearing in the matter subsequent to the notification of the suspension.

Class II (Faulty or Careless) Violations.

Upon the first Class II violation being committed by a manufacturer:

The Commissioner shall send a written "First Notice" to the registrant. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 et. seq. of this rule, and the enforcement policy established by this section of the rule.

The manufacturer shall be assessed a $400.00 penalty for the Class II violation.

The manufacturer shall be given 30 days to fix the Class II violation and must provide evidence to the Department that the violation has been alleviated.

If a second Class II violation has been committed on the same products within a one year period, the Commissioner shall send a written "Second Notice" to the registrant. The registrant must develop a written plan to correct the violation(s) and implement it within 10 business days after the Second Notice has been sent. An additional $800.00 penalty will be assessed for the second Class II violation of a product.

If a third Class II violation has not been resolved within a specified time frame, the Commissioner will issue an immediate "Suspension of Permit".

The "Suspension of Permit" order will give the reason for the order and the length of time the "Suspension of Permit" order will be in effect.

The suspension of permit order shall state the time that the suspension will be effective and give the reason for the suspension. In the case of a summary suspension, the Commissioner may give the manufacturer the opportunity to request a hearing in this matter subsequent to the notification of the suspension.

Class I (Flagrant) Violations.

Upon the first Class I violation being committed by a manufacturer:

The Commissioner shall notify the registrant that the product has been embargoed. This notice shall notify the registrant that a violation of West Virginia Code §19-12E-7 et. seq. of this rule and the enforcement policy established by this section of the rule.

Embargo of products shall follow in accordance with Section 12 of 61CSR30 rule.

The manufacturer of a product with a Class I violation shall be assessed a penalty of $1,000.00

Any person knowingly processing, manufacturing, distributing, or selling hemp derived or kratom products that is contaminated with a toxic or illegal substance is guilty of a felony and shall be fined or imprisoned, as defined in chapter 19 article 12, E and F, as determined by the commissioner.

The embargo notice will establish the date effective and give the reason for the embargo.

A person who performs a recall by voluntarily removing product from sale or distribution in an effective manner, so as to limit the potential harm to the health and well-being of the public, may be eligible for exemptions from the normal enforcement policy. The Commissioner shall consider the facts of each case when making a decision on an exemption.

The Commissioner may suspend the standard enforcement policy in cases where such action is necessary to protect the public health, safety, and welfare.

Law enforcement or any agents other than the commissioner shall work in consultation with the Department prior to and post investigations of any retail establishment or manufacturer.

**Embargos:**

Embargo orders.

When the Commissioner has reasonable cause to believe any lot of hemp or kratom product is being manufactured distributed offered for sale exposed for sale or used in this state in violation of the provisions of this rule a written embargo order may be issued and enforced warning the custodian of the hemp product not to manufacture, distribute, use, remove, or dispose of it in any manner until the embargo is released by the Commissioner or by court order.

When the embargo is issued, the Commissioner shall affix a tag or other marking to the hemp or

kratom product, warning that such product is under embargo and shall notify the custodian of the right to request a hearing.

The Commissioner shall release the hemp or kratom product so embargoed when said product has been brought into compliance.

The Commissioner shall have the authority to issue an embargo against a perishable product even if the result is the involuntary disposal of the product.

The Commissioner may take action to seize and condemn any product if not brought into compliance within the aforesaid time frame.

**Condemnation and Confiscation**

Any hemp or kratom product not in compliance may be subject to condemnation, confiscation, and destruction.

Any party aggrieved by the penalties set forth in this rule shall respond to the Department within 14 calendar days of the infraction. Upon request, the party shall be afforded the opportunity for a hearing before the commissioner under the rules promulgated by the commissioner.

Funding code 1401-8509-6893-6932


**West Virginia Department of Agriculture**

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner


**West Virginia Hemp Product ☐ Seller ☐ Distributor Registration Application**

**January 1, 2024 -December 31, 2024**

| |
|---|
| **Name of Retail Store (or Chain):** |
| **Physical Address of Store where Hemp Products are Sold**<br>*Note: If mobile, please describe business location; If online, please include a web address:* |
| **Mailing Address:** ☐ **Same as above**<br>*(If different than physical address)* |
| **Legal Name of Owner:** |
| **Email address:** |
| **Telephone #:** **FEIN or Tax ID:** |
| **Legal Owner Home Address:** |
| **Store type(s):**<br>☐ **Permanent Building** ☐ **Online** ☐ **Kiosk**<br>☐ **Mobilized Unit / Tent** |


mailing address: 1900 Kanawha Blvd. East, Charleston, WV 25305-0009
physical address: 217 Gus R. Douglass Lane, Charleston, WV 25312
telephone: 304-558-3550 • fax: 304-558-2203

www.agriculture.wv.gov

**Days of Operation and Time:**
*(Check days which apply & complete time store is open)*

☐ **Monday Time**_____ ☐ **Friday Time** _____

☐ **Tuesday Time**_____ ☐ **Saturday Time** _____

☐ **Wednesday Time**_____ ☐ **Sunday Time** _____

☐ **Thursday Time** _____

**Do you only sell products that are manufactured or white labeled by yourself?**

☐ **Yes** ☐ **No**

*(Note: If yes, you are exempt from the seller / distributor fee, but must complete the registration)*

**Note: If you are only a distributor of hemp products in West Virginia and DO NOT engage in retail sales, you are then you are exempt from registration.**

**Registration Checklist**

☐ **Completed the Hemp Product Seller / Distributor Registration Form to Completion**

☐ **Completed a List of Products Intended for Sale, Including the Product Name and Brand**

☐ **Included the Required Annual Registration Fee**

**Name of Responsible Person (Print):**

**Signature:** **Date:**

**Date Received by WVDA:** **Person Receiving:**

**Date Registration Sent by WVDA:** **Approved or Denied:**

All Hemp Product Seller / Distributor Registrations are annually $100 to be paid in U.S. Funds drawn from U.S. Banks. All checks or money orders should be made to the West Virginia Department of Agriculture and mailed to the address below. For any questions, please call 304-558-2227. All registrations will be sent to the applicant upon approval and payment received. It is the responsibility of the retail establishment and/or distributor to ensure all products offered for sale are registered with the WVDA. Return the completed form with check or money order to:

**West Virginia Department of Agriculture**
**Attn:** Administrative Services Division
1900 Kanawha Blvd. East
Charleston, WV 25305-0170

mailing address: 1900 Kanawha Blvd. East, Charleston, WV 25305-0009
physical address: 217 Gus R. Douglass Lane, Charleston, WV 25312
telephone: 304-558-3550 • fax: 304-558-2203

## Hemp and Kratom Product Retailers:

Under WV SB220 the following hemp derived cannabinoids and all kratom products are subjected to an additional 11 percent tax.

**Delta-10-Tetrahydrocannabinol (Delta-10-THC)**

**Delta-9-Tetrahydrcannabinol (THC) <0.3% Total THC**

**Delta-8-Tetrahydrocannabinol (Delta-8-THC)**

**Delta-9-Tetrahydrocannabivarin (Delta-10-THCV)**

**Hexahydrocannabinol (HHC) (-)**

**Tetrahydrocannabiphorol (THCP)**

**All Kratom products**

If you do not sell these products in your retail store, please note on your registration form.

Follow WV Tax Division instructions to register and obtain proof of good standing letter at https://tax.wv.gov. If a letter of good standing has been submitted from previous year, please note on application.

Funding code 1401-8509-6895-6933

**West Virginia Department of Agriculture**

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

## West Virginia Registration of Hemp Products or Extracts Application

**January 1, 2024 – December 31, 2024**

| |
|---|
| **Name of Manufacturer:** |
| **Physical Address where Hemp Products are Manufactured:** |
| **Mailing Address:** ☐ **Same as above**<br>*(If different than physical address)* |
| **Legal Name of Owner:** |
| **Email address:** |
| **Telephone #:** |
| **Name and address of person whose name appears on the product label:** |
| **Manufacturer type(s):**<br>☐ **Fiber** ☐ **Flower** ☐ **Seed** ☐ **Cosmetic**<br>☐ **Oil** ☐ **Edible** ☐ **Vape** ☐ **Other** |

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telephone: 304-558-3550 • fax: 304-558-2203

www.agriculture.wv.gov

| |
|---|
| **Do you only manufacture hemp that you have grown?**<br>☐ **Yes** ☐ **No** |
| **Note: Hemp Fiber products are exempt from the product registration** |
| **Registration Checklist**<br>☐ **Completed the Manufacturer/Registrant Registration of Hemp Products**<br>☐ **Completed a List of Products Manufactured**<br>☐ **Included the Required Annual Registration Fee per Product**<br>☐ **Include copy of each Product Label**<br>☐ **Include copy of WV processing/cultivation license and WV grown approval (If applicable)** |
| **Name of Responsible Person (Print):** |
| **Signature:** **Date:** |
| **Date Received by WVDA:** **Person Receiving:** |
| **Date Registration Sent by WVDA:** **Approved or Denied:** |

Registration fee shall be paid in U.S. Funds drawn from U.S. Banks. All checks or money orders should be made to the West Virginia Department of Agriculture and mailed to the address below. For any questions, please call 304-558-2227. All registrations will be sent to the applicant once approved and upon receiving payment. Complete this form and mail with check or money order to:

**West Virginia Department of Agriculture**
**Attn:** Administrative Services Division
1900 Kanawha Blvd. East
Charleston, WV 25305-0170

mailing address: 1900 Kanawha Blvd. East, Charleston, WV 25305-0009
physical address: 217 Gus R. Douglass Lane, Charleston, WV 25312
telephone: 304-558-3550 • fax: 304-558-2203

**List of Hemp Products Intended for Sale**

Please fill in all spaces with the correct information. Also required for registration of each product listed below; a complete copy of the label and certificate of analysis (please see attached documentation of label and certificate of analysis requirements). If you wish to add additional products for sale after the initial registration, please submit an Amended Hemp Products Registration to hempproducts@wvda.us.

| Product (example: oil, food, smokable flower, etc.) | Full Name of product (Mom's Hemp Full Spectrum Balm with Peach Scent) | Brand (example: Mountaineers are Always Free) | Origin of raw hemp product used to manufacture final product (Name and Address) | State where final product is manufactured | White Labeled (Yes / No) |
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(capped at $1,000 if manufactured and sold in West Virginia)

Total Products_____x $200 per product = Total for all products submitted $_____

mailing address: 1900 Kanawha Blvd. East, Charleston, WV 25305-0009
physical address: 217 Gus R. Douglass Lane, Charleston, WV 25312
telephone: 304-558-3550 • fax: 304-558-2203

# West Virginia Department of Agriculture

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

## West Virginia Registration of Kratom Products or Extracts Application

**January 1, 2024 - December 31, 2024**

| | | | |
|---|---|---|---|
| **Choose one:** | **Manufacturer** ☐ | **Retailer/Seller** ☐ | **Distributor** ☐ |
| | 1401-8512-6893-6841<br>1401-8512-6893-6844 | 1401-8512-6893-6843<br>1401-8512-6893-6846 | 1401-8512-6893-6842<br>1401-8512-6893-6845 |

**Name of Registrant:**

**Physical Address:**

**Mailing Address:** **Same as above** ☐
*(If different than physical address)*

**Legal Name of Owner:**

**Email address:**

**Telephone #:** **FEIN or Tax ID # (Retailer/Seller only):**

**Name and address of person whose name appears on the product label:**

**Product type(s):**

| | | |
|---|---|---|
| ☐ **Tincture** | ☐ **Capsules/Tablets** | ☐ **Powder** |
| ☐ **Extract** | ☐ **Raw Leaf/Flower:** | ☐ **Other:** |

West Virginia Department of Agriculture

Kent A. Leonhardt, Commissioner
Joseph L. Hatton, Deputy Commissioner

Assigned to:
Date Assigned:
Closed Date:

# West Virginia Hemp and Kratom Product Complaint Form

| Details About Yourself | | |
|---|---|---|
| Name of Person Making Complaint | Company | Date |
| Mailing Address of Person Making Complaint | City | State/Zip |
| Email Address | Home Phone # | Work Phone # |
| **Complaint Is About Business or Person** | | |
| Name of Business or Person Complaint Is About | Company | Date |
| Address of Business or Person Complaint Is About | City | State/ZIP |
| Email Address | Home Phone # | Work Phone # |

| Type of suspected violation |
|---|
| ☐ Label |
| ☐ Ingredients |
| ☐ Registration |

WEST VIRGINIA DEPARTMENT OF AGRICULTURE | 1900 KANAWHA BOULEVARD EAST, CHARLESTON, WV 25305

# WV GROWN

# TRADEMARK LICENSING AGREEMENT
# PROGRAM GUIDELINES
# NEW MEMBER APPLICATION

*for*

## PRODUCERS
## RETAILERS AND RESTAURANTS
## SUPPORTERS

*Fillable pdf here:*

agriculture.wv.gov | 304.558.2210

Updated 2.20.23

EMAIL: WVGROWN@WVDA.US

## WV GROWN Program Information

- West Virginia Grown is WVDA's official marketing program for West Virginia food products and the entities that sell, serve and support them. The program's goals are:
    - For consumers to easily identify and purchase agricultural products and value-added items grown and/or manufactured in the state,
    - To expand the overall local foods economy to support farmers, manufacturers and other agribusinesses, and
    - To create a more robust and resilient food system in the Mountain State.

## WV GROWN Program Requirements

- WV Grown Producers: Products must be grown in West Virginia, or manufactured products must have at least 50 percent of their value added within the state. Other requirements may apply (see following page).
- Must be properly labeled according to WVDA labeling standards. Label reviews are a free service of the WVDA, which will issue a certificate of label review for approved labels.
- Some products may require special manufacturing certifications and process approvals. See the WVDA Farmers Market Vendor Guide for details.
- Meat products must be processed and packaged in a facility that is inspected by the United States Department of Agriculture (USDA) or WVDA's Meat and Poultry Inspection Division (MPID). Producers must have a valid Distributor Permit when applicable. Contact MPID at 304-558-2206 for details.
- Dairy products, eggs, hemp, animal feeds and seeds must meet additional regulatory and labeling requirements. The WVDA Regulatory and Environmental Affairs Division (READ) handles the registration and product label reviews for these specific products. Call 304-558-2227 for details. Honeybee colonies must registered with WVDA's Animal Health Division (AHD). Call 304-558-2214 for details.
- WV Grown Partners: Must sell or serve at least one WV Grown product in their retail establishment or food service business. Supporting partners must explain how they further the WV Grown brand and mission.
- Biennial membership renewal is required to help WVDA maintain up-to-date company and product info.

## WV GROWN Program Benefits

- Official Certificate of Membership.
- Use of the WV Grown logo.
- Use of marketing materials available for purchase from the WVDA (see promotional materials request form).
- Inclusion in public member listings.
- Promotional coverage through the WVDA's Market Bulletin, social media platforms, outreach efforts and special events.
- Inclusion in the printed WV Grown member directory (additional information will be requested).
- No cost to join!

## Application Instructions - Mandatory Procedures!

- SATISFY all registration and labeling requirements.
- ENTER company name and address on **Trademark Licensing Agreement** that follows.
- **SIGN** second page of **Trademark Licensing Agreement**
- **SIGN Membership Application**
- COMPLETE application form.
- RETURN to wvgrown@wvda.us

# WEST VIRGINIA GROWN Trademark Licensing Agreement

**Authority:** W. Va. Code §19-1-3a.

**Purpose:** WVDA's mission is to promote the marketing and purchase of agricultural commodities grown, produced, processed, packaged, or manufactured in West Virginia. WVDA is the exclusive owner of the trademarked "West Virginia Grown" Name and Logo (the "Name and Logo"). WVDA wishes to license the Name and Logo for the limited purpose of promoting West Virginia agricultural products. This Agreement establishes the terms and conditions of Licensee's use of the Name and Logo.

The First Party shall be the West Virginia Department of Agriculture.

The Second Party shall be:

Company, Farm or
Individual Name

Mailing Address

1. **License.** WVDA hereby grants to Licensee a limited, worldwide, non-exclusive, non-transferable, license to use the Name and Logo attached hereto on Exhibit A on, or in connection with, Licensee's product offerings in accordance with this Agreement. As used in this Agreement, the term "Name and Logo" shall include the logo affixed on Exhibit A and the term "West Virginia Grown," or either one of the foregoing.
2. **Form of Use.** Unless authorized in writing by WVDA, Licensee shall use the Name and Logo only in the form and manner as the same appears in Exhibit A of this Agreement. Licensee shall not modify the shape, color, appearance, text, font, spacing or other aspect of the Name and Logo, nor shall Licensee add images, slogans, text or other elements to, on or around the Name and Logo; provided that Licensee may use the Name and Logo in a size or sizes of its own choosing.
3. **Use Review.** Upon request by WVDA, Licensee shall submit or make available to WVDA samples of the Licensee's products, artwork, advertising copy, product packages, and depiction of all proposed uses of the Name and Logo.
4. **Scope of Use.** Licensee shall use the Name and Logo only on products, or the packaging of products, which are produced in West Virginia or have at least fifty percent (50%) value added as a result of processing the product in West Virginia. The Commissioner of Agriculture has the sole and final authority to determine the percentage of value added processing, after reasonable, documented inquiry.
5. **Royalty.** Licensee shall not be required to pay a royalty, or any other fee associated with this license agreement.
6. **Reservation of Rights.** The parties to this Agreement recognize and agree that nothing in this Agreement may be construed or argued to have any effect on the WVDA's ownership of the Name and Logo. WVDA expressly reserves the sole and exclusive ownership of the Name and Logo. The Parties agree that, except for the license granted under this Agreement, Licensee shall not have any right, title or interest in or to the Name and Logo. Licensee agrees that it will take no action inconsistent with such ownership and that its use of the Name and Logo shall inure to the benefit of WVDA. WVDA shall retain the exclusive right to apply for and obtain registrations of the Name and Logo and any variations thereof throughout the world. Licensee agrees not to use the Name and Logo, or any confusingly similar mark or name, in its corporate or trade name. Licensee therefore agrees that, except for the rights granted herein, it has no interest in or ownership of the Name and Logo, and further agrees not to register or attempt to register or apply for any trademark, in any jurisdiction, that incorporates the Name and Logo or any confusingly similar mark or name.
7. **Website and Directory.** Licensee understands that WVDA intends to publish the information Licensee provides to WVDA on the West Virginia Grown Membership Application in both print and digital directories and on WVDA-approved websites and social media to further the purposes of the West Virginia Grown program. Licensee expressly agrees to such publication.
8. **West Virginia Freedom of Information Act.** Licensee understands WVDA is a public body that must comply with the West Virginia Freedom of Information Act. All information Licensee provides to WVDA is subject to public release and publication in all forms of media, for all lawful purposes.
9. **Goodwill.** Licensee shall not take any action that would tend to destroy or diminish the goodwill in the Name and Logo. Licensee further agrees that its use of the Name and Logo shall not impugn the WVDA, or any of its divisions, or be unreasonably offensive to the general public. Licensee shall not engage, participate or otherwise become involved in any activity that diminishes or tarnishes the image or reputation of the Name and Logo.

10. **No WVDA Endorsement.** Licensee expressly acknowledges that use of the Name and Logo does not indicate or suggest that WVDA endorses or sponsors any of Licensee's products.
11. **Compliance with Laws.** Licensee's use of the Name and Logo shall comply with all applicable federal, state and local laws, rules and regulations.
12. **Termination.** Unless otherwise terminated by the parties, this Agreement shall remain in full force and effect until further revoked or amended. Either party may terminate this Agreement, with or without cause, by providing fifteen (15) days' written notice to the other party.
13. **Post-Termination Rights and Obligations.** Should WVDA cease to use the Name and Logo, WVDA shall provide Licensee with written notice to discontinue all use of the Name and Logo. If WVDA or Licensee provides written notice of its intent to withdraw from this Agreement, Licensee shall cease affixing the Name and Logo to promotional items and shall withdraw the Name and Logo from publication, wherever possible.
14. **Infringement Proceedings.** WVDA shall have the sole authority and right to prosecute any infringement and any unauthorized use of the Name and Logo, at its sole option. If Licensee learns of any unauthorized use of the Name and Logo, Licensee shall notify WVDA promptly, and, if requested to do so, shall cooperate with and assist, at WVDA's expense, in any infringement action that WVDA may bring.
15. **Indemnification.** Licensee shall indemnify, defend and hold harmless the State of West Virginia and WVDA from and against all claims, liabilities or judgments arising out of or in any way connected with Licensee's activities under this Agreement or Licensee's use of the Name and Logo.
16. **No Warranty.** WVDA makes no representations or warranties with respect to the Name and Logo.
17. **Applicable Law.** West Virginia law controls this Agreement. All disputes arising out of this Agreement shall be brought in Kanawha County, West Virginia.
18. **Notices.** Any notices required or permitted to be sent by one party to the other under this Agreement shall be sent by certified mail to the addresses specified below, or to such other address as a party shall have furnished in writing to the other party.

a. **To WVDA:**
   West Virginia Department of Agriculture
   Attn: Business Development Division
   1900 Kanawha Blvd., East
   Charleston, WV 25305-0170

b. **To Licensee:** To the address shown underneath Licensee's name on page one (1) of this Agreement.

19. **Assignment.** Licensee shall not assign or sublicense this Agreement or its rights hereunder without the written consent of WVDA.
20. **Modification and Waiver.** This agreement may not be amended or modified, except by written agreement, signed by both par-ties. It is agreed that no waiver by either Party hereto of any breach of any of the provisions herein set forth shall be deemed a waiver of any subsequent breach of or default under the same or any other provision of this Agreement.
21. **Severability.** In the event any term or condition of this Agreement is found to be unenforceable by a court of competent jurisdiction, the remaining terms and conditions shall remain in full force and effect.
22. **Integration.** This Agreement contains the entire agreement between WVDA and the Licensee, and supersedes all prior agreements, whether oral or written, between the Parties.

*A typed or esigned signature below constitutes a binding legal agreement*

**Exhibit A**

The "WV Grown" Name and Logo

Applicant Signature

Applicant Esignature

Its: _____, this _____ day of _____, _____
*title* *date* *month* *year*

WVDA Signature

WVDA Esignature

Its: _____, this _____ day of _____, _____

# WEST VIRGINIA GROWN Membership Application

**PRODUCERS - BEFORE you send in this application, you MUST complete the following requirements:**

- ☐ **ACIDIFIED FOODS:** Process Approval, approved food safety training and have a Farmers Market Vendor Permit. Contact 304-558-2210.
- ☐ **DAIRY:** You must be obtain a Dairy Distributor Permit and a Farmers Market Vendor Permit. Contact 304-558-2227.
- ☐ **EGGS:** You must register as a Small Egg Producer. Contact 304-558-2227.
- ☐ **HEMP:** You must register as a Hemp Product Distributor. Contact 304-558-2227
- ☐ **HONEY:** Your must register your apiary. Contact 304-558-2214.
- ☐ **MEAT & POULTRY:** You must obtain a Meat and Poultry Distributor License and a Farmers Market Vendor permit. Contact 304-558-2206.
- ☐ **PRODUCT LABEL REVIEW:** Email request form below and labels to productlabeling@wvda.us. Contact 304-558-2210.

## 1. MEMBER CATEGORY (Mark all that apply):

- ☐ **WV Grown Producer:** I produce, grow or manufacture in WV, or add at least 50% of value in WV. **Complete sections 2, 3 & 7.**
- ☐ **WV Grown "Sold Here":** I am a retail establishment sourcing and selling WV Grown Product(s). **Complete sections 2, 4 & 7.**
- ☐ **WV Grown "Served Here":** I am a food-service establishment sourcing and serving WV Grown Product(s). **Complete sections 2, 5 & 7.**
- ☐ **WV Grown "Supported Here":** I am an individual or organization supporting the WV Grown brand. **Complete sections 2, 6 & 7.**

## 2. APPLICANT INFORMATION:

Business/Farm Name: _____ Contact Person: _____

Phone/Cell: _____ Email: _____

Physical Address:_____ City: _____ State:_____ Zip: _____

Mailing Address: _____ City: _____ State:_____ Zip: _____

County: _____ Facebook: _____ Website: _____ Other: _____

1. Are you a Veteran, First Responder, Fireman, Policeman, etc.? ☐Yes ☐No
2. If yes, would you like more information on the Veterans and Heroes to Agriculture Program ☐Yes ☐No ☐Already a member

****REQUIRED - By e-signing, typing a signature, or hand-writing a signature and submitting this WV Grown application form - REQUIRED****

- I certify that all information given in this application is true, accurate and complete, and that I have the necessary authority to enter into this agreement.
- I understand that providing incomplete, inaccurate or fraudulent information may result in denial or revocation of WV Grown Program membership.
- I understand that membership is at the discretion of the WVDA and may be denied or revoked at any time and for any reason.
- I agree to allow WVDA to share with the public this company's name, products and other non-confidential information.

→ E-Signature: Date: _____

Typed or hand-written signature: _____

## 3. WV GROWN "PRODUCERS" (check all products that apply):

This category is intended for farmers who grow produce, livestock, or similar items - as well as manufacturers of value-added food products that have at least half of their value added inside of West Virginia. Join and show your pride as a WV Grown producer!

- ☐ Adult Beverages
- ☐ Agritourism
- ☐ Aquaculture
- ☐ Baked Goods
- ☐ Bath & Body
- ☐ Beverages (non-alcohol)
- ☐ Candy, Confections & Ice Cream
- ☐ Christmas Trees
- ☐ Condiments
- ☐ Dairy Products/Distributor
- ☐ Eggs
- ☐ Fiber
- ☐ Flours, Meals & Mixes
- ☐ Hemp Products
- ☐ Herbs & Spices
- ☐ Honey & Honey Products
- ☐ Jams, Jellies & Butters
- ☐ Meat & Poultry
- ☐ Orchards & Fruit
- ☐ Pasta, Rice & Legumes
- ☐ Pet Products
- ☐ Pickled/Acidified/Preserved Products
- ☐ Produce
- ☐ Snack Foods
- ☐ Syrups
- ☐ Other _____

## 4. WV GROWN "SOLD HERE"

This category is intended for retail outlets that sell at least one official WV Grown product. Don't feel as though you don't sell enough, or can't keep enough products stocked, to become a member. We want you to help expand the WV Grown brand so that shoppers will demand more, producers will make more, decision-makers will support more, and you will SELL more!

What WV Grown Products do you sell?

Estimated yearly gross of WV Grown product sales (optional, but helps us gauge effect of program)

## 5. WV GROWN "SERVED HERE"

This category is intended for restaurants or other prepared food operations that use at least one official West Virginia Grown product on their menu. Don't feel as though you don't sell enough, or can't keep enough products stocked, to become a member. We want you to help expand the WV Grown brand so that diners will demand more, producers will make more, decision-makers will support more, and you will SELL more!

What WV Grown Products do you use?

Estimated yearly gross of WV Grown product sales (optional, but helps us gauge effect of program)

## 6. WV GROWN "SUPPORTED HERE"

This category is intended to provide supporters of West Virginia agriculture not directly involved in production or sales a way to help expand the WV Grown brand and synergize promotional efforts. Supporters can be any organization or individual committed to the promotion and preservation of West Virginia's farm and food community.

Describe your organization?

How do you support/advance WV agriculture (services, financial, education, advocacy, etc.)

## 7. TELL US YOUR STORY:

Use the space below to tell us about about the history of your company and your products or services. We will use this information to help market your company, so focus on what makes you special in the eyes of the public and what they will find engaging.
ALSO - If you have some great photos to share, email them to wvgrown@wvda.us.

# CONTACTS

## WEST VIRGINIA DEPARTMENT OF AGRICULTURE (WVDA)

**Carrie Summers - Director**
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**Chad Linton - Deputy Director**
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**Millie Taylor - Assistant Director of Programs**
WVDA Regulatory and Environmental Affairs Division
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**Jonathon Davis - Hemp Compliance Officer**
WVDA Regulatory and Environmental Affairs Division
1900 Kanawha Blvd. E. | Charleston, WV 25305
**304-558-2227**
**jdavis@wvda.us**

**Destiny Helmick - Hemp Product Registration Specialist**
WVDA Regulatory and Environmental Affairs Division
1900 Kanawha Blvd. E. | Charleston, WV 25305
**304-558-2227**
**dhelmick@wvda.us**

**John T. Moredock - Hemp Program Coordinator**
WVDA Plant Industries Division
1900 Kanawha Blvd. E. | Charleston, WV 25305
**304-558-2212**
**jmoredock@wvda.us**

# ADDITIONAL LINKS

**WVDA Hemp Products Law/Rule**

http://agriculture.wv.gov/licenses/hemp-and-kratom-products/

**FDA - Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)**

https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd

**FDA - What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD**

https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis

**USDA – National Organic Program**

https://www.ams.usde.gov/about-ams/programs-offices/national-organic-program

**WVU Industrial Hemp Fact Sheet**

http://agriculture.wv.gov/divisions/plant-industries/industrial-hemp/

**WVDA Hemp Testing Laboratory Program**

https://agriculture.wv.gov/wp-content/uploads/2020/06/Hemp-brochure-July-26-changes-MCA.pdf


West Virginia DEPARTMENT OF
AGRICULTURE
COMMISSIONER, KENT A. LEONHARDT