



WEST VIRGINIA SECRETARY OF STATE
KRIS WARNER
ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Agriculture TITLE-SERIES: 61-43
RULE TYPE: Legislative Amendment to Existing Rule: No Repeal of existing rule: No
RULE NAME: 61-43 Select Plant-Based Derivatives And Select Plant-Based Derivative Products-Kratom

PRIMARY CONTACT

NAME: Amie Minor
ADDRESS: WV Department Of Agriculture
1900 Kanawha Boulevard East
Charleston, WV 25305
EMAIL: aminor@wvda.us
PHONE NUMBER: 304-558-3200

CITE STATUTORY AUTHORITY: §19-13-3, 19-13-4

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

§19-12F-1 allows for the registration and regulation of select plant-based derivative products sold within the State of West Virginia.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/24/2026

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/24/2026

COMMENTS RECEIVED: No

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

n/a

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This is a new rule. This rule sets forth guidelines for registration and regulation of select plant-based derivative products sold in West Virginia.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

To regulate kratom products sold in West Virginia, registration process, fees, labeling, advertisement, handling, transport, inspection, testing, enforcement, and penalties.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

Implementation of 61CSR43 giving Kratom and Kratom products a separate legislative rule. Revenue would not change with the addition of this rule. WVDA would continue to incur personnel and operation costs associated with inspection, compliance, and enforcement activities required for a controlled substance.

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

Implementation of 61CSR43 giving Kratom and Kratom products a separate legislative rule. Revenue would not change with the addition of this new rule. The WVDA

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

Implementation of 61CSR43 giving Kratom and kratom products a separate legislative rule. Revenue would not change with the addition of this rule. The WVDA would continue to incur personnel and operation costs associated with inspection, compliance, and enforcement activities required for a controlled substance.

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2026 Increase/Decrease (use "-")	2027 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

No revenue changes

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Amie J Minor -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE
LEGISLATIVE RULE
WEST VIRGINIA DEPARTMENT OF AGRICULTURE

SERIES 43
SELECT PLANT-BASED DERIVATIVES AND
SELECT PLANT-BASED DERIVATIVE PRODUCTS-KRATOM

§61-43-1. General.

1.1. Scope. -- This legislative rule provides for the registration and regulation of select plant-based derivative products sold within the State of West Virginia.

1.2. Authority. -- W. Va. Code §19-12F-1 et seq.

1.3. Filing Date. --

1.4. Effective Date. --

1.5. Sunset Date. -- This rule shall terminate and have no further force or effect on August 1, 2036.

§61-43-2. Definitions.

2.1 "Alcohol Beverage Control Administration Commissioner" means the West Virginia Alcohol Beverage Control Administration Commissioner or his or her designee.

2.2. "Commercial sales" means the sale of products in the stream of commerce direct to the endpoint consumer.

2.3. "Commissioner" means the Commissioner of Agriculture or his or her designee.

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

2.5 "Contaminated" means made impure and unsafe by biological, chemical, or physical additives.

2.6. "Crop" means *Mitragyna speciosa* (hereafter "kratom") grown under a single registration.

2.7. "Department" or "Department of Agriculture" means the West Virginia Department of Agriculture and its employees.

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

2.9. "Dose" means a single serving of a kratom product as identified on the product label by the manufacturer for one-time human consumption. For whole leaf, crushed leaf, or powdered kratom products, the dose shall be the labeled serving size or recommended amount per serving.

2.10. “Embargo” means to remove a product or products from circulation by confiscation.

2.11. “Embargo order” means a written order issued by the Commissioner directing a manufacturer, distributor, retailer, or other person in possession or control of kratom or a kratom product to immediately cease the sale, distribution, or offering for sale of specified kratom or kratom products pending further action by the Commissioner.

2.12. “Final product” means the product that is packaged and is ready to be made available to the consumer by distribution or sale.

2.13. “Grower” means any person, joint venture, cooperative, or entity that grows kratom for commercial purposes.

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

2.15. “Informational panel” means any part of the label that is not the primary label.

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

2.17. “Kratom” means a psychoactive preparation that is composed of the crushed or powdered dried leaves of the *Mitragyna speciosa*, a lowered tropical tree which contains the alkaloids mitragynine and 7-hydroxymitragynine.

2.18. “Kratom product” means the natural leaf of the plant *Mitragyna speciosa* and any simple physical form of the leaf, including whole, crushed, or powdered. “Kratom product” does not include a product that has been synthetically manipulated or chemically concentrated beyond the leaf’s natural alkaloid profile. Kratom products shall be limited to these natural leaf forms and shall not include tablets, beverages, liquid shots, food products, or any other formulated or processed consumable delivery system. The legal limit of 7-hydroxymitragynine (7-OH) must be no greater than 10 milligrams per dose.

2.19. “Lot” means any amount of kratom product of the same type and processed at the same time using the same ingredients, standard operating procedures, and batches.

2.20. “Manufacturer” or “processor” means a person who or entity which compounds, converts, or processes kratom into any commodity or product.

2.21. “Manufacturing” means compounding, converting, or processing raw kratom into any commodity or product.

2.22. “Permittee” means any person or entity/entities with a permit issued by the Department to manufacture, distribute or sell select plant-based derivative products.

2.23. “Person” means any corporation, individual, partnership, organization, or society.

2.24. “Plant-based” means derived or made from plants.

2.25. “Primary label” means the part of the label to be prominently displayed to the consumer at retail.

2.26. “Processing” means converting an agricultural commodity, or a non-agricultural commodity specified as a select-plant based derivative into a marketable form.

2.27. “Products covered under West Virginia Code 19-12F-1 et seq” means products which are naturally occurring, and non-synthetic substances that are derived from kratom (*Mitragyna speciosa*) plants.

2.28. “Retail facility” or “retail establishment” means the physical location from which select plant-based derivative products are sold direct to consumers.

2.29. “Select Plant-Based Derivative” means plant-derived compounds referring to materials or ingredients that originate from plants.

2.30. “Summary Suspension” means an order issued by the Commissioner that immediately suspends a permit issued under this rule and prohibits the permit holder from manufacturing, distributing, selling, offering for sale, or otherwise engaging in activities authorized by the permit.

2.31. “White label” means a manufactured *Mitragyna speciosa* product that is manufactured or processed by one person or entity but sold by another person or entity under their own label.

§61-43-3. Regulatory authority.

3.1. The Department has the authority to regulate kratom products for the purposes of consumer protection and public safety. The Department further has the authority to approve or deny registration of products. The Department may deny the registration of a product considered to be potentially hazardous, as well as products that pose a threat to consumer safety or are otherwise considered to be harmful. The Department shall deny or revoke registration of any kratom product that contains any amount of kava (*Piper methysticum*), valerian root, yohimbe bark, willow bark, California poppy, *Boswellia serrata* resin, *Corydalis yanhusuo*, passion flower, psychoactive mushrooms, cannabinoids, or phytocannabinoids. The Department shall also deny or revoke registration of any kratom product that contains any natural or synthetic ingredient that is intended to, or could be reasonably anticipated to, enhance, potentiate, or synergize the pharmacological, psychoactive, intoxicating, or physiological effects of kratom.

3.2. The Department shall maintain records and systems necessary to track registrations, inspections, enforcement actions, and referrals in accordance with W. Va. Code §19-12F-12.

§61-43-4. Permitting and Registration of kratom products or extracts.

4.1. The Commissioner may issue manufacturer, processor, distributor, product, and retail permits. Any person offering for sale or is selling kratom products must obtain the required permit, and all kratom products available for distribution or sale in West Virginia, including products manufactured in West Virginia, another state, or another country, shall be registered by the permittee annually with the Department as specified by the application provisions for product registrations in 4.2 of this rule.

4.1.a. Effective June 12, 2026, the Department shall not approve or register any kratom product that is not in a form permitted under subdivision 2.18 of this rule, including but not limited to tablets, beverages, liquid shots, or food products.

4.2. Applications for permittees seeking to register kratom product(s) shall be made to the Department on a registration form provided by the Department available on the Department's website, and shall include the following information:

4.2.a. The name and address of the registrant;

4.2.b. The name and address of the person whose name shall appear on the label, if different from the registrant's;

4.2.c. The name of the product;

4.2.d. The origin of the raw kratom from which the final product was manufactured;

4.2.e. A complete copy of the label that will appear on the product; and

4.2.f. The associated registration fee, as indicated below.

4.3. Registrations shall expire on December 31 of the year for which the registration was issued, regardless of the date the registration is received.

4.4. The application for registration will be due by January 1 of each calendar year.

4.5. A separate registration fee of \$200.00 for each kratom product shall be paid to the Department with the submission of the application. 4.5.a. The white labeler is responsible for, and will be subject to, all fines and enforcement actions related to white labeled products in accordance with state law.

4.5.b. Kratom products with the same chemical composition and concentration but different net quantities will qualify as one product.

4.6. The Department may deny or delay registrations and renewals that are incomplete or erroneous and have had no action taken by the applicant for 60 calendar days.

4.7. A new registration is required for any of the following:

4.7.a. Changes in the chemical composition, concentration or formula of the kratom product; or

4.7.b. Changes to health-related label claims for active ingredients.

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

4.9. As a condition of registration, all registrants are required to retain documentation for a minimum of two years after the final product manufacture date for each product lot demonstrating the source of the kratom that was utilized to manufacture the kratom product, including documentation that the product was grown by a licensed kratom grower. Such documentation shall be made available to the Department upon request.

4.10. Notwithstanding Subsections 2.18 and 4.1.a of this rule, any kratom product in a form otherwise prohibited by this rule that was registered with the Department prior to June 12, 2026, may remain registered and may continue to be sold or distributed until December 31, 2026, unless sooner suspended, revoked, or found to be in violation of this rule.

§61-43-5. Registration to distribute and sell kratom products.

5.1. Each retail facility, including online domains and websites, is required to register with the Department for a permit to sell kratom products in West Virginia. Per W. Va. Code §19-12F-8(g), the Commissioner shall maintain and publish a list of all permits issued each year, which is available on the Department's website.

5.2. Applications to sell and distribute kratom products shall be made to the Department on a form provided by the Department, which is available on the Department's website, and shall include the following information:

5.2.a. Name and address of the applicant's retail store; or, if the applicant is selling through an online store, such must be indicated on the form;

5.2.b. Name and home address of the responsible party;

5.2.c. The associated registration fee;

5.2.d. Letter of good standing with the West Virginia State Tax Division;

5.2.e. A list of all distributors from whom retailers receive product(s); and

5.2.f. A West Virginia Business registration certificate.

5.3. A nonrefundable application fee of \$1,500 shall be paid to the Department for a permit to manufacture, process, distribute, or sell kratom products in West Virginia.

5.4. An annual registration fee of \$300 shall be paid to the Department with the submission for application to manufacture, process, distribute, or sell kratom products in West Virginia.

5.5. A registration fee shall be paid annually. Registrations shall expire on December 31 of the year for which the registration is issued, regardless of the date the registration is received.

5.6. Registrations shall be due on January 1 annually.

5.7. Retail establishments that sell only kratom 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.

5.8. The Department may deny or delay registrations and renewals that are incomplete or erroneous and have had no action taken by the applicant for 60 calendar days.

5.9. 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 kratom products. This certificate will be issued annually. The correct and accurate certificate must be displayed at all times at the retail facility.

5.9.a. Retailer/Distributor registrations issued by the Department are nontransferable and valid only for the specific person, entity, and physical location identified on the application and registration certificate.

5.9.b. A change in ownership, transfer of business operations, or change in retail location shall require a new registration application and approval by the Department prior to the sale or distribution of kratom products at the new location.

5.9.c. Each retail location operating within the state shall obtain a separate registration, regardless of common ownership or affiliation.

5.10. The Department may revoke the registration of a retail facility to sell kratom products if it determines the facility has sold products to individuals not meeting requirements of Subsection 7.12 of this rule. The Commissioner shall keep a list of any persons or entities that have been subject to a permit revocation, withdrawal, suspension, non-renewal, or other process whereby the person or entity has ceased to be a permit holder in good standing with the Commissioner. The Commissioner shall keep a list of all kratom products that have been approved for sale or distribution in this state. Such list shall be public information and shall be published by the Commissioner on its website from time to time so as to reflect a current listing.

§61-43-6. Displays, Advertising, and Marketing.

6.1. For establishments selling kratom products intended for consumption, products shall be displayed only in areas that the store staff can see in direct sight or behind counters that deny public access.

6.2. For establishments, stores at fairs and festivals, farmers' markets, etc., products must be in a controlled environment and not accessible to children.

6.3. Advertising on television, online, by radio, and in print is prohibited when 30% or more of the listener/viewer/user group is comprised of persons under the age of 21.

6.4. The distribution of free samples of kratom products intended for consumption is prohibited, except for products distributed in an "adult-only facility."

§61-43-7. Labeling.

7.1. 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.

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

7.3. Kratom products shall not contain disease or drug claims on the label that are not approved by the FDA.

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

7.5. Product labels must be clear and legible.

7.6. Labels must be printed in English.

7.7. The following labeling is forbidden:

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

7.7.b. The product cannot be attractive to children. This includes, but is not limited to:

7.7.b.1. The use of cartoons, cartoon characters, superheroes, television shows, video games, movies, or other similar characters or references;

7.7.b.2. The use of images popularly used to advertise to children; or

7.7.b.3. The imitation of a candy or food label.

7.7.c. The label cannot include false or misleading information. This includes untrue or unproven information that leads consumers to have an inaccurate impression.

7.7.d. The label cannot include the use of the word “organic” unless referencing certified organic products that have been certified as organic in accordance with the National Organic Program, as provided for by the USDA.

7.8. Kratom product labels will be considered misbranded when, upon analysis, the Department finds that the alkaloid content declared on the label is false, misleading, or not supported by analytical findings.

7.9. The following requirements must be met for the primary label:

7.9.a. The product must be identified with the generic or common name; and

7.9.b. If the product label claim contains any amount of mitragynine or 7-hydroxymitragynine, the label must properly identify them.

7.10. The following requirements must be included on the information panel:

7.10.a. Manufacturer’s name and contact information;

7.10.b. Batch or lot number;

7.10.c. Instructions for use and any preparation needed, if applicable;

7.10.c.1. The label shall include the serving size or recommended dose and the number of servings per container, if applicable.

7.10.d. List of all ingredients in descending order by weight or volume;

7.10.e. Allergens, if applicable;

7.10.f. Artificial food coloring, if applicable;

7.10.g. Expiration or use by date, if applicable;

7.10.h. Refrigeration or refrigerate after opening warnings, if perishable after opening; and

7.10.i. For edible products, sodium, sugar, carbohydrates, and total fat per serving.

7.10.j. The net weight or volume of the contents of the package, in both metric and US customary units must be displayed.

7.10.j.1. For capsules, soft gels, or similar products, the contents statement can be a combination of weight or volume.

7.11. The Mitragyna and 7-hydroxymitragynine content in milligram form must be posted on either the primary or informational panel, and must include:

7.11.a. Any product label claiming a guaranteed kratom alkaloid content shall disclose all relevant alkaloids, including mitragynine and 7-hydroxymitragynine, and the total amount of the claimed alkaloid content per package for all manufactured products; and

7.11.b. The kratom alkaloid content per serving, including mitragynine and 7-hydroxymitragynine, shall be provided for all kratom products with designated serving sizes.

7.12. Any product containing kratom derivatives must declare on the label, “NOT INTENDED FOR SALE TO PERSONS UNDER THE AGE OF 21”; “Keep out of 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.”

7.12.a. It is unlawful to manufacture, package, import, distribute, or sell any kratom product without the required label. The label is to be written in English using legible type and shall be placed in a conspicuous location on the outer packaging.

7.13. 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 Subsections 7.11 and 7.12 and subdivision 7.10.i of this rule.

§61-43-8. Handling and transport.

8.1. It is lawful in West Virginia to transport and possess kratom products, so long as the 7-hydroxymitragynine content does not exceed that permitted by law.

8.2. 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.

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

8.4. Kratom products cannot be legally sold to anyone under the verified age of 21.

8.4.a. For direct, in-person transactions, the seller shall verify that the purchaser is at least twenty-one (21) years of age through examination of a valid government-issued photographic identification and/or an age verification scanning device.

8.4.b. Any website owned, managed, or operated by a person who manufactures, processes, distributes, offers for sale, or sells kratom products to persons in this state shall verify that a purchaser is twenty-one (21) years of age or older prior to the completion of a sale.

8.4.c. Age verification required by Subsection 8.4.b shall be satisfied by requiring the individual to:

8.4.c.1. Provide digital identification; or

8.4.c.2. Comply with a commercial or governmental age verification system that verifies age using:

8.4.c.2.a. Government-issued identification, including digital identification; or

8.4.c.2.b. A commercially reasonable method that relies on public or private transactional data to verify the individual's age.

8.4.d. Any person or entity distributing, offering to distribute or sell, or selling kratom products to persons in this state by means other than a direct, in-person transaction shall utilize an age-verification mechanism approved by the Commissioner.

8.5. A licensed retailer may employ whom he or she pleases so long as:

8.5.a. An employee must be at least eighteen (18) years of age in order to sell kratom products to customers.

8.5.b. An employee must be at least twenty-one (21) years of age to take delivery of kratom products at a warehouse.

8.5.c. A retail outlet may employ a person between sixteen (16) and eighteen (18) years of age to work in a retail outlet; provided, the Commissioner has given written approval beforehand to employ such person, and (b) the person will not be permitted to sell or deliver kratom or kratom products. The authorization to employ persons under eighteen (18) years of age must be clearly stated on the registration certificate.

§61-43-9. Inspection and testing.

9.1. The Department shall conduct random inspections of kratom and kratom products distributed, made available for distribution, or offered for sale in the state.

9.2. The Department shall periodically sample, analyze, and test kratom and kratom products distributed within the state, or offered for sale in the state, for compliance with registration, labeling requirements, and product safety, if applicable.

9.3. The Department may conduct inspections and investigations of kratom, kratom products, and regulated entities as necessary to determine compliance with this rule.

9.3.a. The Department may enter and inspect any premises, retail establishment, storage facility, or location where kratom or kratom products are manufactured, processed, packed, stored, distributed, sold, or offered for sale within the state for purposes of determining compliance with registration, labeling, testing, product safety, and all other applicable requirements of this rule.

9.3.b. The Department may inspect and copy records related to the manufacture, distribution, sale, registration, sourcing, testing, or transfer of kratom or kratom products to determine compliance with this rule.

9.4. Samples taken by the Department will be the official samples for the purposes of determining compliance with this rule and for imposing the administrative penalties provided in this rule.

9.5. Law enforcement, agents other than the Commissioner, and consumers may submit samples of kratom or kratom products to the Department for testing, provided that (a) the party requesting the test pays the associated fees set by the Commissioner, and (b) the sample is accompanied by a detailed chain of custody upon submission to the Department.

9.6. Samples that are found to contain contaminants in excess of the limits set by the Department will be considered Contaminated. The Department will maintain a list of contaminants and the associated limits on its website.

9.6.a. Pesticide limits, residual solvent and processing chemical limits, toxic metal limits, microbiological limits for ingestible and inhalable products, mycotoxin limits, water activity, and foreign materials limits may be found on the Department's website. Limits set by the Department are subject to the following:

9.6.a.1. The limit for ethanol does not apply to products that are intended to be orally consumed and contain alcohol; and

9.6.a.2. The limit for ethanol or isopropyl alcohol does not apply to products that are intended to be topical products.

9.6.b. The Department may modify the maximum limits for contaminants at any time or from time to time.

§61-43-10. Enforcement actions on all kratom product violations and related penalties.

10.1. The Commissioner may assess administrative penalties for violations of this rule and W.Va. Code §19-12F-1, et seq.

10.2. Violations shall be classified according to severity, as follows:

10.2.a. Class I Violations include the following:

10.2.a.1. Distributing, manufacturing, or offering for sale kratom or kratom products that are unsafe, Contaminated, or present an immediate human or animal health concern;

10.2.a.2. Offering for sale kratom or kratom products with 7-hydroxymitragynine over 10 milligrams per dose and non-naturally occurring and fully synthetic products;

10.2.a.3. Third offense registration violations;

10.2.a.4. Improper labeling, as defined in Subsections 7.9.b and 7.12 of this rule;

10.2.a.5. Advertising or Marketing violations, as defined in Section 6 of this rule;

10.2.a.6. Offering for sale kratom or a kratom product for which the Department has denied registration or which the Department is unable to register; and

10.2.a.7. Continuing to offer for sale kratom or a kratom product after Class III or II final notice has been issued, or while a permit is under a summary suspension, or while a product is subject to an embargo order.

10.2.b. Class II Violations include the following:

10.2.b.1. Submission of false, inaccurate, or misleading information on an application;

10.2.b.2. Failure to specify serving size and frequency of use on the kratom or kratom product label as required by this rule; and

10.2.b.3. Distributing, manufacturing, or offering for sale kratom or a kratom product that fails to meet its label claims or is misbranded.

10.2.c. Class III Violations are all other violations of W. Va. Code § 19-12F-1, *et seq.*, and this rule not specifically identified in Subsections 10.2.a. or 10.2.b. or in Sections 11 or 12.

10.3. Class III Violations.

10.3.a. Upon an initial Class III violation:

10.3.a.1. The Commissioner shall send a written “First Notice” to the individual or entity containing a short and plain description of each violation of this rule or W. Va. Code § 19-12F-1, *et seq.*;

10.3.a.2. The individual or entity will be assessed a \$200.00 fine for each Class III violation;

10.3.a.3. All unlawful kratom and kratom products, and all kratom or kratom products unlawfully possessed or offered for sale, will be embargoed by the Department and destroyed; and

10.3.a.4. The individual or entity will be given 30 calendar days following the date of the First Notice to correct all violations of this rule and provide evidence thereof to the Department via letter or email to hempproducts@wvda.us.

10.3.b. If a second Class III violation is found within one calendar year following the date of the “First Notice”:

10.3.b.1. The Commissioner shall send a written “Second Notice” to the individual or entity containing a short and plain description of each violation of this rule or W. Va. Code § 19-12F-1, *et seq.*;

10.3.b.2. The individual or entity will be assessed a \$500.00 fine for each Class III violation;

10.3.b.3. All unlawful kratom and kratom products, and all kratom and kratom products unlawfully possessed or offered for sale, will be embargoed by the Department and destroyed; and

10.3.b.4. The individual or entity must develop a written plan to remedy all violations and implement such written plan within 10 business days after the Second Notice has been sent.

10.3.c. If a third Class III violation is found within one calendar year following the date of the "First Notice," the Commissioner shall (a) issue a fine of \$1,000 per Class III Violation; (b) embargo and destroy all unlawful kratom and kratom products, and all kratom or kratom products unlawfully possessed or offered for sale; and (c) issue an immediate summary suspension order, embargo order, or both. The Commissioner may also refuse to grant or renew any retailer, distributor, or manufacturer permit required to sell, distribute, or manufacture kratom or kratom products in this state.

10.3.c.1. The order will contain a short and plain statement of the reason for the order, the effective date of the order, and the length of time for which the order will be in effect, which may be indefinite.

10.3.c.2. If an individual or entity subject to an order issued under this Subsection 10.3 contests the order, the individual or entity shall bring such contestation in writing within 14 calendar days of when the order takes effect.

10.4. Class II Violations.

10.4.a. Upon an initial Class II violation:

10.4.a.1. The Commissioner shall send a written "First Notice" to the individual or entity containing a short and plain description of each violation of this rule or W. Va. Code § 19-12F-1, et seq.;

10.4.a.2. The individual or entity will be assessed a \$400.00 fine for each Class II violation;

10.4.a.3 All unlawful kratom and kratom products, and all kratom or kratom Products unlawfully possessed or offered for sale, will be embargoed by the Department and destroyed; and

10.4.a.4. The individual or entity will be given 30 calendar days following the date of the First Notice to correct all violations of this rule and provide evidence thereof to the Department via letter or email to hempproducts@wvda.us.

10.4.b. If a second Class II violation is found within one calendar year following the date of the "First Notice":

10.4.b.1. The Commissioner shall send a written "Second Notice" to the individual or entity containing a short and plain description of each violation of this rule or W. Va. Code § 19-12F-1, et seq.;

10.4.b.2. The individual or entity will be assessed an \$800.00 fine for each Class II violation;

10.4.b.3. All unlawful kratom and kratom products, and all kratom or kratom products unlawfully possessed or offered for sale, will be embargoed by the Department and destroyed; and

10.4.b.4. The individual or entity must develop a written plan to remedy all violations and implement such written plan within 10 business days after the Second Notice has been sent.

10.4.c. If a third Class II violation is found within one calendar year following the date of the "First Notice," the Commissioner shall (a) issue a fine of \$1,000 per Class II Violation; (b) embargo and destroy all unlawful kratom and kratom products, and all kratom or kratom products unlawfully possessed or offered for sale; and (c) and issue an immediate summary suspension order, embargo order, or both. The Commissioner may also refuse to grant or renew any retailer, distributor, or manufacturer permit required to sell, distribute, or manufacture kratom or kratom products in this state.

10.4.c.1. The order will contain a short and plain statement of the reason for the order, the effective date of the order, and the length of time for which the order will be in effect, which may be indefinite.

10.4.c.2. If an individual or entity subject to an order issued under this Subsection 10.4 contests the order, the individual or entity shall bring such contestation in writing within 14 calendar days of when the order takes effect.

10.5. Class I Violations.

10.5.a. Upon an initial Class I Violation, the Commissioner shall (a) issue a fine of \$1,000 per Class I Violation; (b) embargo and destroy all unlawful kratom and kratom products, and all kratom or kratom products unlawfully possessed or offered for sale by reason of a Class I Violation; (c) send a written notice to the registrant that describes the product or products that have been embargoed and contains a short and plain statement of each violation of this rule or W. Va. Code § 19-12F-1, et seq.; and (d) issue an immediate summary suspension order, embargo order, or both. The Commissioner may also refuse to grant or renew any retailer, distributor, or manufacturer permit required to sell, distribute, or manufacture kratom or kratom products in this state.

10.5.a.1. The order will contain a short and plain statement of the reason for the order, the effective date of the order, and the length of time for which the order will be in effect, which may be indefinite.

10.5.a.2. If an individual or entity subject to an order issued under this Subsection 10.5 contests the order, the individual or entity shall bring such contestation in writing within 14 calendar days of when the order takes effect.

10.6. A person who performs a recall by voluntarily removing product from sale or distribution in an effective manner, 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 review the facts of each case when considering an exemption.

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

10.8. Law enforcement or any agents other than the Commissioner shall work in consultation with the Department before, during, and after investigation of any retail, distribution, or manufacturing establishment.

10.9. The Alcohol Beverage Control Administration Commissioner may utilize its enforcement agents or persons to conduct investigations and enforcement related to underage sales of products. The Alcohol Beverage Control Administration shall notify the Department before an enforcement action occurs, when an enforcement action is occurring, and after an enforcement action is completed.

10.10. Nothing in this rule shall limit or supersede criminal penalties established under W. Va. Code §19-12F-11. Violations of this rule may be referred to appropriate law enforcement authorities or prosecuting attorneys for criminal enforcement.

§61-43-11. Enforcement actions on unregistered retailers, manufacturers, and distributors covered under West Virginia Code § 19-12F-1, et seq.

11.1. If the retailer, distributor, retailer, or manufacturer does not register at all, or does not renew the registration annually, the Commissioner is authorized to take enforcement actions against the retailer, distributor, or manufacturer as set forth in this Section.

11.2. Upon the first offense:

11.2.a. The retailer, distributor, or manufacturer will be notified in writing that they must register with the Department, and that the sale, distribution, or manufacture of kratom and kratom products without registration is prohibited;

11.2.b. The retailer, distributor, or manufacturer will be given 15 business days from the date of the notice to register with the Department; and

11.2.c. All kratom and kratom products shall be embargoed and destroyed.

11.3. Upon the second offense within one calendar year following the first notice of violation:

11.3.a. The distributor, retailer, or manufacturer will be notified in writing of their failure to register with the Department;

11.3.b. All kratom or kratom products will be immediately embargoed and destroyed;

11.3.c. The retailer, distributor, or manufacturer will be issued a notice of violation and be required to pay a fine of \$1,000; and

11.3.d. The retailer, distributor, or manufacturer will be ineligible to apply for a permit from the Department for one calendar year.

11.4. Upon a third offense within one calendar year following the first notice of violation:

11.4.a. The retailer, distributor, or manufacturer will be notified in writing of their failure to register with the Department and the retailer, distributor, or manufacturer will be permanently ineligible to apply for registration with the Department;

11.4.b. The Department shall embargo and destroy all kratom and kratom products; and

11.4.c. The distributor, retailer and/or product manufacturer shall be required to pay a fine of \$1,000.

11.5. Any person or entity seeking to contest a suspension of eligibility to register with the Department under this Section shall bring such contestation in writing within 14 days after the issuance of the notice of ineligibility.

11.6. Law enforcement or any agents other than the Commissioner shall work in consultation with the Department before, during, and after investigation of any retail, distribution, or manufacturing establishment.

§61-43-12. Enforcement actions on unregistered products covered under West Virginia Code § 19-12F-1, et seq.

12.1. If any retailer, distributor, or manufacturer that is required to register a product fails to register a product or fails to renew the product registration annually, the Commissioner is authorized to take enforcement actions against the retailer, distributor, or manufacturer as set forth in this Section.

12.2. Upon the first offense:

12.2.a. The retailer, distributor, or manufacturer will be notified in writing that they must register the product with the Department, and that the sale, distribution, or manufacturing of unregistered kratom or kratom products is prohibited;

12.2.b. The retailer, distributor, or manufacturer will be given 15 business days from the date of the notice to register the kratom or kratom product with the Department; and

12.2.c. All kratom and kratom products shall be embargoed and destroyed, and an embargo order will be issued and remain in effect until the kratom or kratom product is brought into compliance.

12.3. Upon the second offense within one calendar year following the first notice of violation:

12.3.a. The retailer, distributor, or manufacturer will be notified of their failure to register the kratom or kratom product, and the retailer, distributor, or manufacturer will be assessed a fine of \$1,000 per unregistered kratom or kratom product;

12.3.b. All unlawful kratom or kratom products will be immediately embargoed and destroyed; and

12.3.c. The Department shall enter an embargo order for the unregistered kratom or kratom product, or a summary suspension order for the retailer, distributor, or manufacturer's permit, or both an embargo or order and summary suspension order, which will be in effect for one calendar year.

12.4. Upon a third offense within one calendar year following the first notice of violation:

12.4.a. The retailer, distributor, or manufacturer will be notified in writing of their failure to register the kratom or kratom product with the Department and that their eligibility to register the kratom or kratom product will be suspended permanently;

12.4.b. The Department shall embargo and destroy all kratom and kratom products; and

12.4.c. The retailer, distributor, or manufacturer will be assessed a fine of \$1,000 per unregistered kratom and kratom product.

12.5. Any person or entity seeking to contest an embargo order or summary suspension issued under this Section shall bring such contestation in writing within 14 days after the issuance of the embargo order or summary suspension order.

12.6. Law enforcement or any agents other than the Commissioner shall work in consultation with the Department before, during, and after investigation of any retail, distribution, or manufacturing establishment.

12.7. The provisions of this Section 12 do not apply if the kratom or kratom product is not capable of being registered under the requirements of this rule, or for which the Department has denied registration.

§61-43-13. Embargos and Embargo Orders; Fines Cumulative; Payment of Fines.

13.1. Embargo Orders.

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

13.1.b. The Commissioner may embargo a perishable product even if the result is the involuntary disposal of the product.

13.1.c. The Department may hold an embargoed product for 60 days before destroying it.

13.1.d. Any person or entity seeking to contest an embargo order issued under this rule shall bring such contestation in writing within 14 days after the issuance of the embargo order.

13.2. The fines and other administrative penalties authorized by this rule are cumulative and not mutually exclusive. A person or entity that commits more than one violation of W. Va. Code § 19-12F-1, *et seq.*, or this rule may be separately assessed for each violation and may be subject to any combination of fines and administrative penalties authorized by W. Va. Code § 19-12F-1, *et seq.*, or this rule.

13.3. Payment of fines.

61CSR43

13.3.a. All fines assessed by the Commissioner under this rule must be paid in a manner approved by the Commissioner within 90 days, or before the date on which a retailer, distributor, or manufacturer must renew a permit or product registration, whichever is sooner.

13.3.b. All fines owed by a retailer, distributor, or manufacturer must be paid before the Department will issue a permit or approve a product registration.

13.3.c. If any individual or entity fails to pay a fine within the time period provided in Subsection 13.3.a., the Commissioner may take action to collect the fine.

13.3.d. The failure to timely pay a fine assessed under this rule may constitute grounds for the denial, suspension, revocation, or nonrenewal of any license or permit issued under this rule.