

West Virginia Department of Agriculture

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



July 25th, 2025

TO: *Holistic Alternatives Recovery Trust ("HART"), Inc.*

ATTN: Mr. Jonathan Miller, General Counsel

Via E-Mail (mjackson@fbilaw.com; jeff@hartsupporter.com; jmiller@fbilaw.com) & *By Publication*
(at Code of State Rules; www.sos.wv.gov)

RE: Response to Public Comment from *Holistic Alternatives Recovery Trust ("HART"), Inc.*
(WVDA's Emergency Rule Filing (W.Va. CSR § 61-30-1, *et seq.* relating to Select Plant-Based Derivatives))

Dear Mr. Miller, (HART, Inc.) & To Whom It May Otherwise Concern:

I am writing in reply to your comment to the West Virginia Department of Agriculture's (hereinafter "WVDA" or "the Department") proposed emergency rule (§61-C.S.R.-30; Select Plant-Based Derivative Products), as received by the Department's Legislative Rule Comment email (rulescomments@wvda.us) on July 10, 2025, at 10:12am, EST.

Thank you for taking the time to submit the above-mentioned correspondence. Below, I will address the three (3) matters at hand which I have identified from your correspondence and will do so in order of your inquiries as they were received. Your comments posed three (3) questions or suggestions for revision as follows:

(1) First, the proposed amendment is ambiguous because the phrase "7-hydroxymitragynine products" is not defined under West Virginia law or elsewhere in the other proposed amendments to 61CSR30. It is not clear which products would be considered "7-hydroxymitragynine products" under 61-30-11 or whether any exceptions would apply. Again, because 7-OH is a naturally present alkaloid in kratom extract, all kratom extract products contain some amount of 7-OH and conceivably could be considered a 7-OH product under the proposed amendment. The indefiniteness of the phrase "7-hydroxymitragynine products" would therefore lead to uncertain, and unintended, regulatory consequences.

(2) Second, relatedly, the proposed amendment to 61-30-11 does not indicate which ingredient or substance "7-hydroxymitragynine products" are restricted to "2 percent" of. Does the restriction mean that 7-OH products are limited to 2 percent of 7-OH, or are they restricted to 2 percent of something else?

To address your first and second remarks and requests for clarity and/or revision: after careful consideration of your comments, we will be modifying our proposed amendment as follows:

"Hemp products containing THC in greater amount(s) than what is authorized by applicable laws, products derived from Mitragyna Speciosa containing more than 2% of 7-hydroxymitragynine, and non-naturally occurring or synthetic products as defined in Section 2.30 of this Rule, such as concentrated 7-OH ("7-OH-MIT" or "7-OH")."

The above change should address your first two comments. While much time was spent in consideration of and in formulating the proposed change as presented in our initial emergency amendment proposal, we also recognize the respective needs of those (*e.g.*, industry/industries) involved in this process.

At the heart of the regulations discussed herein lies our fundamental intent to help foster the growth of hemp, kratom, and other select plant-based derivative industries' business in this state to allow for an already-thriving industry to flourish. After all, agriculture has a fundamentally significant part in all realms; but more specifically to this issue, agriculture plays a critical role in promoting the economic growth of our great state.

That said, it is important to note that we are constitutionally obligated to provide safe, healthy products; therefore, we must seek to ensure that any product(s) under the umbrella of our regulatory authority which are sold to West Virginia consumers are, indeed, what they claim to be.

Given that the nature of the product(s) discussed herein, and the broad range of consumer goods therewith, I will now take the opportunity to note that some products under the umbrella of the Department's authority do have the potential to be marketed and sold as a health or medicinal product and are perhaps legally marketed and sold as such at the present moment. Therefore, we must take all possible measures to strike a balance between the above-noted constitutional/regulatory obligations and our commitment to furthering economic growth and prosperity as the new and dangerous synthetic forms of these products continue to evolve virtually overnight.

In further consideration of our duty to protect the citizens of this state, we believe that it is necessary to maintain a tight and science-based threshold (the 2% limit) to be in line with the standard which our nationally renowned (ISO 17025 accredited) laboratory considers to be the appropriate, most properly considered as what we know to be safe, and scientifically accurate standard. This must be done to best ensure quality levels and safety in monitoring the content of all items and products regulated by WVDA.

To address your third and final point as to suggested language, and while noting the appreciation of such input, I will begin by reiterating my statement concerning our constitutionally mandated duties to ensure the safety of West Virginia consumers.

This duty applies to all that we do, both in the oversight of quality levels as relevant to any given product(s), as well as the standard(s) to which the product(s) under our purview are held. We believe that the percentage requirements act to ensure that we uphold our obligations to West Virginia citizens.

Your third and final inquiry was as follows:

(3) Third, the proposed amendment to 61-30-11 is further ambiguous because the word "synthetic" is not defined. Accordingly, manufacturers and sellers are left to guess as to whether

their products are “synthetic” or not. We think this confusion and uncertainty can be easily avoided with minor revisions. We recommend the following revised language:

Hemp products that contain more than the THC content authorized by law, kratom products that contain more than 28mg of 7-hydroxymitragynine per serving, 112mg of mitragynine per serving, and 150mg of kavalactones per serving, and non-naturally occurring/fully synthetic products.

These recommended changes are consistent with the enabling statutes’ focus on kratom and kratom products, as opposed to 7-OH products generally. The changes better reflect how kratom and kratom products are marketed to consumers, which typically is based on milligrams per serving or per container, not percentages of derivative ingredients. Moreover, nothing in West Virginia code section 19-12F-5—the authority cited for the proposed amendments to 61CSR30—directs the Department to impose a 2 percent limit, as opposed to a limit based on milligrams per serving. Finally, adding the word “fully” before “synthetic” will ensure that 7-OH products, which are manufactured from naturally occurring kratom alkaloids, are not treated as unlawful and can continue to be purchased and used by the West Virginians who rely on them.

The Department agrees that the term “synthetic” as used in the Rule and as amended by the proposed emergency filing should be clarified. Resultantly, we will revise the proposed emergency rule and its amendment pertaining to your third point as follows:

2.30. “Products covered under by West Virginia Code §§19-12E-12 and 19-12F-5” means product(s) which are naturally occurring, non-synthetic substances that are derived from hemp (Cannabis Sativa L) or kratom (Mitragyna Speciosa) plants; and for the purposes of this rule, synthetic refers to products covered under §§19-12E-12 and 19-12F-5, which are not derived naturally from the plant(s), but are instead created and produced in a laboratory setting (e.g., entirely lab-made products are considered to be synthetic.)

The Department declines, however, to adopt the entirety of your suggested revisions as to *kavalactones* and serving(s) in milligrams, as our adopted regulation currently does not incorporate *kavalactones* and does not follow a milligram-by-serving framework.

If there are more specific concerns, please call our Regulatory Division at the telephone number listed on this letterhead to speak with one of WVDA’s highly qualified employees, each of whom is specialized in their respective field(s). I suggest that you call or email any specific questions or needs so that we can best assist you with further inquiries and can more easily answer any future questions that may arise about product labeling requirements.

I will note in sum, however, that we do find our requirements to be on par with the various other restrictions that exist elsewhere across the country, and some states have taken far more stringent steps, including flat bans and more intensive regulatory measures.

The restrictions on the classification of certain forms of kratom and its chemical makeup, including its numerous scientific compounds and components, as well as the items made

therefrom and therewith, are following what exists in state code or as mandated by law or regulation. These products and kratom overall is marketed to certain varieties of consumer products which are intended to be marketed or sold as medicinal or dietary items, or those which can have potential risks or health implications.

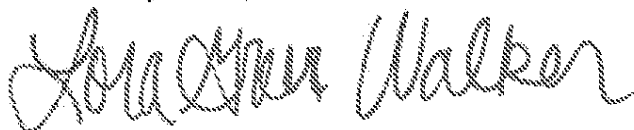
This fact in itself warrants appropriate restrictions as to content and the levels or amount that each of those said item(s) and product(s) sold may contain, just as the Department has in place with this regulatory framework, and which the Department will continue to enforce.

Indeed, the FDA recently issued a warning on July 15th, 2025, (just a few short days following your comment on our proposed emergency amendment to this Rule) regarding the illegal marketing of certain products as potentially concerning. I have attached a copy of the warning received by the Department via email to this Letter.

I will emphasize that the Department does feel that this approach, as proposed, and as now revised based on your remarks, is a reasonable, science-based approach and an attempt to accommodate both consumer safety and industry needs in WVDA's regulatory practices as the FDA seeks further response and clarity from the entities which received the official warning as to these products.

Again, I thank you for your input and suggestions as to appropriate language for this Emergency Rule, and I do hope this has provided you with the answers and clarification needed.

Sincerely Yours,

A handwritten signature in cursive script that reads "Lora Greer Walker". The signature is written in black ink and is positioned above the typed name.

Lora Greer Walker, Esq., General Counsel

West Virginia Department of Agriculture