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DH, MMRegulations

From: Pamela Epstein <pamela@edenenterprises.com>
Sent: Monday, April 5, 2021 4:15 PM
To: DH, MMRegulations
Subject: [External] Eden Enterprises Comments on PROPOSED RULEMAKING Medical Marijuana Proposed Regulations - Section 1151a.27(f)
Attachments: Eden Enterprises Comments on PROPOSED RULEMAKING Medical Marijuana Proposed Regulations - Section 1151a.27(f).pdf

Dear Director Collins,Please see the attached comments on PROPOSED RULEMAKING Medical Marijuana Proposed Regulations - Section 1151a.27(f).Respectfully submitted,
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April 5, 2021

John J. Collins, Director, Office of Medical Marijuana
Department of Health
Health & Welfare Building, Room 628
625 Forster Street
Harrisburg, PA 17120
RA-DHMMregulations@pa.gov
SUBMITTED VIA ELECTRONIC MAIL

RE: **Comments on PROPOSED RULEMAKING Medical Marijuana Proposed Regulations - Section 1151a.27(f).**

Dear Director Collins,

These comments are in response to the Pennsylvania Department of Public Health's (the "Department" or "DOH") request for input on proposed regulations. Terpene Belt Processing, LLC ("Terpene Belt") is a subsidiary of Eden Enterprises, Inc. ("Eden"). Eden is a vertically integrated cannabis and hemp operator based out of California with nearly two decades of experience. Terpene Belt is a purveyor of high-quality hemp-derived terpenes that are free of cannabinoids. Terpene Belt partners with regulated marijuana producers to provide 2018 Farm Bill compliant hemp-derived terpenes for use in their marijuana products. Eden has also worked with and supported regulators across the country on the inclusion of hemp-derived ingredients in regulated marijuana products.

Terpene Belt is committed to excellence in its operations and the advancement of public health and safety in manufactured marijuana products. To that end, we look forward to being a trusted source of responsible information for the Department. Our comments and recommendations seek to ensure the necessary balance between efficiencies, innovation and consumer safety.

I. Inhalable and Ingestible Medical Marijuana Products Require Different Treatment with Respect to "Added Substances."

Terpene Belt commends the DOH for continuing to advance a pre-approval rhetoric. This is an effective control for when new substances that alter the smell and taste are added to marijuana products during the manufacturing process. It is important; however, to address the often overlooked distinction between how the human body's digestive and respiratory systems function and more importantly process substances. It is imperative that DOH apply the correct standard for assessing the safety of a substance based on the category of product and the method of

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consumption. This direction is consistent with other states such as Florida which is currently proposing to regulations to address inhalable versus ingestible.[1]

The FDA's Generally Recognized as Safe Standard (more commonly known as "GRAS") designation is applicable to foods as defined in Section 201(f) of the Federal Food Drug, and Cosmetic Act. Specifically, food is designated as "(1) articles used for food or drink for man or other animals, (2) chewing gum, (3) articles used as components for any such article." The GRAS program is focused on foods that are safe for human consumption. Accordingly, its application in determining if an "additional substance" is safe for products meant for inhalation is not only irrelevant, but also has great potential for confusion, misrepresentation and harm.

Vitamin E acetate and the EVALI outbreak of 2019 is the ideal case study to highlight the importance of understanding and harmonizing how different bodily systems process ingredients. For example when vitamin E acetate is inhaled via vaporization it is acutely and chronically harmful, even deadly; however, when ingested in food, it is harmless.[2] In fact, vitamin E acetate has received FDA GRAS designation for use in food.

A. <u>The DOH should modify Section 1141a.21 and 1151a.27(f) to address different permissible ingredients in inhalable marijuana products versus others manufactured marijuana products.</u>

The DOH is proposing regulatory amendments to subsection (f) of Section 1151a.27 requirements for growing and processing medical marijuana, which would change the term "additional active ingredient or material" to "added substance." The regulatory amendment further proposes to add two considerations for use by DOH in determining whether to pre-approve the "added substance" ingredient: (1) whether the added substance is permitted by the FDA for use in food or is GRAS and (2) whether the added substance constitutes a known hazard.

As discussed above, we recommend distinguishing between permissible added substances for ingestible medical marijuana products and permissible added substances for inhalable medical marijuana products. Acting upon the knowledge obtained from the EVALI crisis, the Department can take proactive steps to protect the health and safety of Pennsylvania citizens by expressly

[1] Recommendation is consistent with the direction of other States, such as Florida. Florida is currently clarifying its existing rule on hemp extract for human consumption; expressly, distinguishing between hemp intended for inhalation and hemp intended for ingestion.
https://www.flrules.org/gateway/ruleno.asp?id=5K-4.034

[2] Grady, Denise, "Vaping Illnesses Are Linked to Vitamin E Acetate, C.D.C. Says," The New York Times, November 8, 2019, https://www.nytimes.com/2019/11/08/health/vaping-illness-cdc.html. 35 "For Healthcare Providers." and Blount, Benjamin, Mateusz Karwowski, Peter Shields, Maria Morel-Espinosa, Liza Valentin-Blasini, Michael Gardner, Martha Braselton, et al, "Vitamin E Acetate in Bronchoalveolar-Lavage Fluid Associated with EVALI," The New England Journal of Medicine, February 20, 2020, 697–705, https://doi.org/DOI:

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prohibiting substances known to be hazardous to human health. Squalene[3], squalane, vitamin E acetate, triglycerides including MCT oil, and propylene glycol when used in the manufacture of inhalable marijuana products have been confirmed as known hazards resulting in acute or chronic harm.

We recommend the Department join states such as Oregon[4], Colorado[5] and Washington[6] who have proactively regulated and prohibited the use of Vitamin E Acetate and other known hazardous substances in vaporized cannabis products.

II. DOH Should Further Distinguish "Additional Substances," Specifically Between Marijuana and non-Marijuana Additives Related to Inhalables.

To learn and apply lessons from past experiences ensures regulatory adaptability and efficiency for licensees. The EVALI crisis was a wake-up call to regulators, operators and consumers. We support the State's intention to be informed and to in turn provide that information to consumers. We equally support ease of process with respect to securing necessary approvals. It is with that context we strongly urge the State to distinguish between marijuana and non-marijuana substances specifically, as it relates to inhalable vaporized marijuana products. Hemp and marijuana is a difference without a distinction. The proverbial two sides of the same coin. Marijuana and hemp are genetically and molecularly identical. As such, they should be afforded similar treatment with respect to the use of terpenes as a flavoring agent and distinguished from non-marijuana substances/additives.

The Cannabis Sativa L plant contains a vast array of chemical compounds. The most relevant to flavor and fragrance are terpenes and terpenoids. Terpenes are not unique or exclusive to cannabis. Flavoring aromatics can be found in other plants, animals or be synthetically derived. The majority of terpenes found in cannabis are hydrocarbons and include most commonly myrcene, β-caryophyllene, αhumulene, α-pinene, linalool, limonene, and ocimene.[7] Terpenes occur naturally in the cannabis plant and can be removed and reintroduced later in a subsequent manufacturing

[3] Fiume, Monice, "Final Report on the Safety Assessment of Squalane and Squalene," 39 (Squalane boiling point of 350°C and squalene at 335°C).
[4] Section 845-025-3265 - Inhalable Cannabinoid Product Processor Requirements https://casetext.com/regulation/oregon-administrative-code/chapter-845-oregon-liquor-control-commission/division-25-recreational-marijuana/section-845-025-3265-inhalable-cannabinoid-product-processor-requirements
[5]https://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=9303&fileName=1%20CCR%20212-3
[6] WAC 246-80-021 prohibiting the use of Vitamin E Acetate in cannabis vapor products (https://app.leg.wa.gov/wac/default.aspx?cite=246-80-021&pdf=true). As of March 31, 2021 Washington is seeking to enhance their enforcement reach with additional penalties for those who violate the prohibition on Vitamin E Acetate https://lcb.wa.gov/sites/default/files/publications/rules/2021%20Proposed%20Rules/WSR%2021-08-035%20NTS%20Rev.pdf
[7] Judith K. Booth and Jörg Bohlmann, "Terpenes in Cannabis Sativa – From Plant Genome to Humans," Plant Science 284 (2019): 68, https://doi.org/10.1016/j.plantsci.2019.03.022

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process. Terpenes are volatile and lost during the manufacturing process to arrive at marijuana thc distillate (oil). The resulting thc distillate is flavorless. Terpenes are then added back in as flavoring. The addition of terpenes as a flavoring function is meant to mimic the flavor of certain marijuana cultivars such as "Jack Herer", "OG Kush" or "Blue Dream."

For scalability and cost efficiency terpenes can be sourced from non-marijuana sources. Those non-marijuana sources may be botanical or syntenic derived. Those non-marijuana substances are logically distinguishable from marijuana and hemp terpenes (collectively "marijuana" for purposes of inhalable vaporized products). Unlike marijuana terpenes non-marijuana flavoring can introduce flavoring such as watermelon, grape which are attractive to children and may result in harm to consumers. For example, a commonly used terpene linalool can be sourced from marijuana or lavender. If a patient knows they can safely consume cannabis but has a lavender allergy there is potential for harm. If there is no distinction (and no additional labeling) between whole plant natural marijuana products and those with "added substances" or "non-marijuana additives," there is simply no ability for the consumer to make an informed decision. Furthermore, non-marijuana flavoring companies are not regulated for inhalable products even though they may suggest that their products are "pharmaceutical-grade and/or GRAS and approved for other purposes such as ingestion," their safety for use in vaping is unknown at best.[8]

Similar to cultivation of medical marijuana, compliantly grown hemp is subject to regulatory oversight. All hemp is required to undergo pre-harvest testing to ensure the crop is below .3% thc. The hemp ingredients incorporated into downstream manufactured medical marijuana products will be subject to regulatory compliance testing as a final form marijuana product. Our position is in alignment with the comments proposed changes recommended by the Pennsylvania Hemp Steering Committee with one important distinction regarding hemp derived cannabinoids versus hemp additives. We believe hemp additives such as terpenes should be able to be sourced from any State with a 2018 hemp complaint Farm Bill program or equivalent. This is an important clarification given that hemp flavoring additives carry no detectable cannabinoids and will allow for quality controlled scalability while ensuring patient safety and financial accessibility.

III. Recommended Language Modifications

Consistent with the spirit of 71 P.S. § 745.5b(b)(1)(ii), the below changes to§ 1141a.21 and 1151a.27(f) prevent the adverse effect on pricing the Department's suggested language may enact.

§ 1141a.21 Definitions

[8] Bryan Duffy, Lingyun Li, Shijun Lu, Lorie Durocher, Mark Dittmar, Emily Delaney-Baldwin, Deepika Panawennage, David Lemaster, Kristen Navarette, and David Spink, "Analysis of Cannabinoid-Containing Fluids in Illicit Vaping Cartridges Recovered from Pulmonary Injury Patients: Identification of Vitamin E Acetate as a Major Diluent," Toxics 8, no. 1 (2020): 15, https://doi.org/10.3390/toxics8010008.

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Added Substance - Any additional ingredient added to medical marijuana during or after processing that is present in the final product or any substance used to change the viscosity or consistency of a cannabinoid product. Ingredients and derivatives derived from industrial hemp shall not be considered an added substance under this section so long as all industrial hemp and hemp derivatives are obtained from a licensed or registered hemp grower or processor, regardless of the grower's or processor's home state. Hemp and hemp derivatives may not be used to synthesize intoxicating compounds including delta-9 tetrahydrocannabinol or delta-8 tetrahydrocannabinol.

Terpenes - Naturally occurring hydrocarbons found in essential oil secreted from the marijuana or industrial hemp plant. Terpenes sourced from industrial hemp must be obtained from a licensed or registered hemp grower or processor, regardless of the grower's or processor's home state.

§ 1151a.27 Requirements for growing and processing medical marijuana

(f) A grower/processor may not use any added substance that alters the dosage level, color, appearance, smell, taste, effect or weight of the medical marijuana unless the grower/processor has first obtained the prior written approval of the Department. Ingredients, derivatives, and terpenes derived from industrial hemp shall not require prior-written approval from the Department. Excipients must be pharmaceutical grade, unless otherwise approved by the Department. The Department shall consider the following when evaluating added substances for approval:

(i) For ingestible medical marijuana products whether the added substance is permitted by the United States Food and Drug Administration for use in food or is Generally Recognized as Safe (GRAS) under federal guidelines;

(ii) For inhalable medical marijuana products, all non-medical marijuana or hemp added substances shall require pre-approval from the Department and be consistent with subsection (iii); and

(iii) Whether the added substance constitutes a known hazard such as, but not limited to, diacetyl, CAS number 431-03-8, and pentanedione, CAS number 600-14-6. For purposes of inhalable vaporized medical marijuana products the following substances are known to be a hazardous and prohibited squalene, squalene, vitamin E acetate, triglycerides including MCT oil, and propylene glycol.

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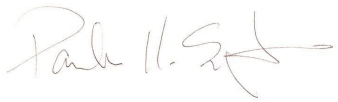
IV. Conclusion

We strongly support the State's commitment to ensuring public health and safety. With that intention in mind, we encourage the Department to take an assertive approach distinguishing between inhalable and ingestible medical marijuana products and between marijuana and non-marijuana substances. In so doing, the Department will alleviate duplicative and incompatible requirements and foster progressive, effective and efficient regulation.

Respectfully Submitted,



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