COLORADO
Department of Revenue
Enforcement Division – Marijuana

November 18, 2019

INDUSTRY-WIDE BULLETIN: 19-07

RE: New Health and Safety Rules Specific to Vaporizers & Request to Immediately Cease the Manufacture and Sale of Vaporizers Containing Vitamin E Acetate

Dear Marijuana Industry Stakeholders:

The Department of Revenue's Marijuana Enforcement Division (Division) is issuing this Industry-Wide Bulletin on new rules adopted in response to recent reports of lung-related illnesses associated with the use of vaporizer products, and to enhance overall health and safety measures in the manufacturing and labeling of regulated marijuana products in Colorado. These rules reflect the results of extensive stakeholder engagement and recommendations. The adopted rules establish the following ingredient restrictions and prohibitions, as well as record keeping, labeling, and other health and safety requirements, effective January 1, 2020.

Ingredient Restrictions:
Pursuant to Rule 3-335(H), 1 CCR 212-3, inactive ingredients used in the manufacture of regulated marijuana intended for use through a vaporizer delivery device or pressurized metered dose inhaler are limited to the following[1]:

- Inactive ingredients listed on the Federal Food and Drug Administration Inactive Ingredient Database for the inhalation route of administration; or
- Inactive ingredients approved by another equivalent international government agency for the inhalation route of administration. Examples of equivalent international government agencies include the European Medicines Agency (Europe) and National Agency for Food and Drug Administration and Control (Canada).

Ingredient Prohibitions:
Rule 3-335(L), 1 CCR 212-3, expressly prohibits the use of the following ingredients in the manufacture of regulated marijuana concentrate or regulated marijuana products intended for inhalation:

- Polyethylene glycol (PEG);
- Vitamin E Acetate; and
- Medium Chain Triglycerides (MCT Oil)

Beginning **January 1, 2020**, Medical and Retail Marijuana Products Manufacturers may not manufacture or transfer regulated marijuana concentrate or products intended for inhalation that do not comply with the above noted ingredient restrictions and prohibitions. Further, beginning **January 1, 2020**, Medical and Retail Marijuana Stores may not take possession of or transfer concentrate or products that do not comply with these ingredient restrictions and prohibitions. Please also refer to the request to comply with these rules as soon as practicable and to immediately cease the manufacture and sale of vaporizers containing Vitamin E Acetate, further below.

[1] The ingredient restrictions reflected in Rule 3-335(H), 1 CCR 212-3 do not apply to marijuana-derived ingredients or botanically-derived terpenes.

Labeling:

Rule 3-1010(C), 1 CCR 212-3, establishes additional labeling requirements for vaporizer delivery devices and pressurized metered dose inhalers containing regulated marijuana. Every Child-Resistant Container and any Marketing Layer for vaporizer delivery devices and pressurized metered dose inhalers must be affixed with a label displaying the following:

- A list of all Ingredients, including **Additives** (referred to herein as the "Ingredient List Requirement"); and
- A warning label that states: **"Not approved by the FDA"** (referred to herein as the "Warning Label Requirement").

With regard to the Warning Label Requirement, Rule 3-1010(C) requires this warning label to be affixed directly to the vaporizer delivery device or pressurized metered dose inhaler. However, recognizing the challenges posed by the size of these devices, manufacturers can comply with this requirement by affixing the warning to the Child-Resistant Container and any Marketing Layer holding the device or inhaler, in lieu of affixing the warning directly to the device or inhaler. Further, notwithstanding the Rules' January 1, 2020 effective date, the Division is providing the following guidance regarding the timeline for compliance with the Ingredient List Requirement and Warning Label Requirement:

- **Medical and Retail Marijuana Products Manufacturers:**
  - **Ingredient List Requirement**: Beginning **January 1, 2020**, Medical and Retail Marijuana Products Manufacturers may not transfer regulated marijuana vaporizer delivery devices or pressurized metered dose inhalers that do not comply with the Ingredient List Requirement. For any devices or inhalers transferred to Medical or Retail Marijuana Stores prior to **January 1, 2020**, to the extent the label for such devices or inhalers do not already include Additives on the ingredient list pursuant to Rules M 1002-1(C)(3)(j) and R 1002-1(C)(3)(h)[2], the Division encourages the Manufacturer to make the complete ingredient list available on its website for patients and consumers.
  - **Warning Label Requirement**: Medical and Retail Marijuana Products Manufacturers will have through **July 1, 2020** to comply with the Warning Label Requirement. Therefore, beginning **July 1, 2020**, Manufacturers may not transfer regulated marijuana vaporizer delivery devices or pressurized metered dose inhalers that do not display the warning label as described above.

- **Medical and Retail Marijuana Stores:**
  - **Ingredient List Requirement**: Beginning **January 1, 2020**, Medical and Retail Marijuana Stores may not take possession of regulated marijuana vaporizer delivery devices or pressurized metered dose inhalers that do not comply with the Ingredient List Requirement. However, any devices or inhalers that were transferred to Stores prior to **January 1, 2020**, and do not comply with the Ingredient List Requirement may be transferred to patients and consumers through **January 1, 2021**.
  - **Warning Label Requirement**: Beginning **July 1, 2020**, Medical and Retail Marijuana Stores may not take possession of regulated marijuana vaporizer delivery devices or pressurized metered dose inhalers that do not comply with the Warning Label Requirement. However, any devices or inhalers that were transferred to Stores prior to **July 1, 2020**, and do not comply with the Warning Labeling Requirement may be transferred to patients and consumers through **January 1, 2021**.

[2] See also Rule 3-1010(C)(3)(i), 1 CCR 212-3.

Record Keeping:

Rules 5-310(F) and 6-310(F), 1 CCR 212-3, require Medical and Retail Marijuana Products Manufacturers to obtain and maintain certificates of analysis or other records demonstrating the full composition of each Ingredient used in the manufacture of vaporizer delivery devices and pressurized metered dose inhalers. Rule 3-905 requires that licensees maintain these records for the preceding six months on the Licensed Premises, which must be provided to the Division on-demand during normal business hours.

Existing and New Health and Safety Requirements

Health and safety requirements established under prior rules remain in effect and include, but are not limited to, the following: Rules M 604, 605, and 607, 1 CCR 212-1, and Rules R 604, 605, and 607, 1 CCR 212-2. Additionally, all required testing pursuant to Rules M and R 712 and the M and R 1500 Series Rules remain in effect.

Adopted rules also reflect industry-led initiatives that demonstrate the state's shared interest in establishing best practices in the manufacture and sale of regulated marijuana products, including additional requirements to evaluate and address nonconformances through corrective actions and preventive actions[3], and to prepare written procedures regarding recalls of regulated marijuana concentrate and regulated marijuana product[4], both of which are effective **January 1, 2021**.

Request to Cease the Manufacture and Sale of Vaporizers Containing Vitamin E Acetate

As of the date of the issuance of this bulletin, the majority of the reports nationwide indicate that products potentially responsible for illnesses in vaping-related cases were obtained from informal sources like friends, family, in-person or online dealers. However, the State of Colorado, both regulators and industry representatives alike, have expressed a shared interest and responsibility to prioritize public health and safety by establishing standards for regulated marijuana that can work to prevent or minimize any ties of such illnesses to regulated marijuana. To that end, and in light of recent findings by the Centers for Disease Control and Prevention identifying Vitamin E Acetate in samples from patients with associated lung injuries, **the Department of Revenue's Marijuana Enforcement Division strongly encourages licensees to comply with these rules as soon as practicable, and requests that licensees at a minimum immediately cease the manufacture and sale of any regulated marijuana vaporizer delivery devices containing Vitamin E Acetate**. See CDC website Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping Products.

The Colorado Department of Revenue's Marijuana Enforcement Division, in partnership with the Colorado Department of Public Health and Environment (CDPHE), continues to carefully monitor reports regarding lung related illnesses associated with the use of vaporizer products. For updates on vaping-associated illness reports in Colorado, please visit the CDPHE's Colorado Vaping-Associated Illness Outbreak Report.

Sincerely,

Jim Burack, Director
Marijuana Enforcement Division

[3] See Rules 5-115, 5-210, 5-310, 6-110, 6-210, and 6-310
[4] See Rules 5-330 and 6-330