#3290

DH, MMRegulations

From: Lindsay Witmer <lindsay.witmer@EthosCannabis.com>
Sent: Friday, October 14, 2022 10:36 AM
To: DH, MMRegulations
Subject: [External] Comments on Regulations

Dear Laura Mentch,

Below are my comments regarding the regulations recently issued. Please let me know if you have any questions or would like to discuss further.

Requirement for Growers/Processors to Utilize Different Laboratories for Testing Marijuana at Different Phases in the Production Process

1171.a.29 Testing Requirements Subsection (c) was amended to state that one approved laboratory must conduct testing on the harvest sample and a different approved laboratory must conduct testing on the processed sample.

Act 44 of 2021 includes language indicating that grower/processors are required to contract with "one or more independent laboratories."

The requirement to use two different labs at different points in the manufacturing process is not defined in Act 44 of 2021 and furthermore no language in the Act dictates this requirement. Requiring that G/Ps utilize two labs drives cost up for patients with no additional benefit.

The Department of Health (DOH) has stated that "lab results are inflated to reflect higher THC percentages than the product actually contains." To address the issue of inflated lab results, the DOH should implement common quality control practices for medical marijuana laboratories, instead of placing a second laboratory requirement on grower/processors.

In quality control, test method development and validation is a critical requirement to ensuring the test results are accurate and precise. Medical device and pharmaceutical companies rely heavily on robust test method development and validation methods to ensure that their quality control testing is consistent and of the highest standard. The FDA requires test method development and validation activities be completed for the product they regulate to ensure test results are accurate and precise.

The DOH should require the medical marijuana testing laboratories to comply with standard test method development and validation requirements. They should also require the medical marijuana testing laboratories to comply with document control, record retention, calibration, preventive maintenance, and other good manufacturing practices. By holding the marijuana testing laboratories to these standards, the testing results provided from those laboratories will be more accurate and precise. This will benefit the patient, keep costs down and be a win for the broader medical marijuana community.

Dispensary Camera Watching Requirement:

In the Final Form Regulations 1161a.31. Security and surveillance (5) it states: The dispensary shall designate an employee or employees to continuously monitor the security and surveillance systems at the facility.

This language has been interpreted by the DOH to require a designated employee be at physically at each dispensary to monitor the cameras on-site. Allowing for remote monitoring of the live feed in one centralized

location for all dispensary locations during business hours would provide the same level of safety and security for the dispensary while decreasing operational costs. Typically, the individual who monitors the cameras during business hours is responsible for alerting the authorities in case of a safety event and is not the individual who would respond to an incident. That responsibility falls on another individual. Technology has allowed for an individual remotely monitoring the cameras to have the same capability of alerting authorities, in an equal capacity, as the individual physically monitoring the cameras at the dispensary. It is not necessary for an individual to be physically in each dispensary. This causes redundancy and drives up cost.

Decreasing these undue operational costs by implementing safety focused efficiencies helps drive down product costs for patients.

Best Regards, Lindsay Witmer

Lindsay Witmer
Ethos Cannabis
Vice President of Regulatory, Compliance & Quality
Lindsay.Witmer@EthosCannabis.com
302-249-9220