



Protecting, maintaining and improving the health of all Minnesotans

**Medical Cannabis Laboratory Testing Requirements,
Rulemaking Advisory Committee
November 28, 2016 1:00 – 3:45 PM
Meeting Minutes**

The meeting was held on the campus of Concordia University in St. Paul, MN

Introductions

Committee members introduced themselves and their organization or interest in the medical cannabis rule.

Overview of the Process

MDH staff provided an overview of rulemaking requirements under Minnesota law, rough timelines expected to be followed, and an overview of the finalized laboratory requirements that will be in effect until the rulewriting is complete.

Roundtable – Identify Topics

General consensus among stakeholders that potency/stability will be important issue and that there is the potential to streamline the process.

Group consensus that the current rule on label requirements should be part of the rulemaking and that changes could be beneficial for the program.

- Example offered by LeafLine Labs’ contingent: passing safety testing is implied by the product being on the shelf; can label just say “passed required state safety testing”?

Rachel Loeber, LeafLine Labs, explained that if the process could reduce the number of necessary retests, costs could be reduced. Also, allowing greater variance for the secondary cannabinoids would result in fewer retests.

- Variation of secondary and trace components is greater because of measurement variability.

Larger question of how cannabinoids are or should be specifically targeted by the law (for testing or labelling requirements).

Kurtis Hanna, patient/consumer advocate, agreed that label could identify “trace” of cannabinoid that is present in very small measure, e.g. 2% of total cannabinoid formulation

Stability Testing

Roger Pearson, Aspen Labs, brought up possibility of 40°C/short-term stability testing.

Stability testing:

- Gary Starr, LeafLine, suggested T_0 be used as stability reference because it's a confidence interval. Using T_0 shows actual degradation of the product and allows trend analysis versus utilizing the label value.
- Roger Pearson, Aspen Labs, suggested some relevant questions for the group are “is the product meeting label definition?”; “how much degradation is allowable?”; “what is it degrading into? Something toxic, more potent, etc.?”
- How much product needs to be submitted for stability testing?
- Roger Pearson: example calculations should be contained in the final rule
- Multiple preparations would reduce uncertainty

Ryan McNamara pointed out the need to define “chemical composition,” as that term is used in the statute

Future Meeting Agenda Topics

- Next meeting, we will have draft language to edit regarding safety, potency, and stability testing. We will also look at the label requirements rule in conjunction with the laboratory testing requirements.

Future Meeting Dates

- Will be announced when room availability is determined.
- At a minimum, the group will meet once in January, once in February, once in March, and once in April.