RECEIVED
Apr 09 2021
Independent Regulatory Review Commission

DH, MMRegulations

From: Josh Rakes <Josh@farmaceuticalrx.com>
Sent: Saturday, April 3, 2021 1:51 PM
To: DH, MMRegulations
Cc: Rebecca Myers
Subject: [External] Medical Marijuana Proposed Rulemaking Input
Attachments: Proposed Rulemaking Medical Marijuana FarmaceuticalRX040321.pdf

ATTENTION: *This email message is from an external sender. Do not open links or attachments from unknown sources. To report suspicious email, forward the message as an attachment to CWOPA_SPAM@pa.gov.*

Director Colin,

Please find attached Proposed Rulemaking Medical Marijuana FarmaceuticalRX040321.pdf. We thank you for your considering and would be happy to clarify further, if needed.

Regards,

JOSH RAKES
DIRECTOR OF COMPLIANCE
Office: 724.856.0277
Email: Josh@farmaceuticalrx.com

FarmaceuticalRX: Our Innovation is your Future Health
www.farmaceuticalrx.com

FARMACEUTICALRX

TO: Director, John J. Collins
Office of Medical Marijuana, Department of Health
Room 628, Health and Welfare Building
625 Forster Street, Harrisburg, PA 17120

From: Josh Rakes, Director of Compliance

Date: April 2nd, 2021

Subject: PROPOSED RULE MAKING MEDICAL MARIJUANA PROPOSED REGULATIONS PUBLIC COMMENTS

Director Collins,

FarmaceuticalRX GP18-6014 operating in Farrell PA, would like to thank the Department of Health and the Commonwealth of PA for the opportunity to provide our public comments regarding the publication of proposed permanent regulations relating to the Commonwealth's medical marijuana program. It is through these exercises that the Office of Medical Marijuana has the opportunity to improve the future of medical marijuana in the Commonwealth.

PROPOSED: § 1171a.29. Testing requirements.

(c) At a minimum, testing, as prescribed by the Department, shall be performed as follows:

(1) An approved laboratory shall test samples from a harvest batch or harvest lot prior to using the harvest batch or harvest lot to produce a medical marijuana product.

(2) An approved laboratory **other than the one that tested the harvest batch or harvest lot shall test samples from each process lot** before the medical marijuana is sold or offered for sale to another medical marijuana organization.

These proposed changes will negatively impact the ability and speed at which operates are able to get products to the market. These revisions will delay cultivation and product workflows, reduce operational efficiencies and disrupt delivery schedules. The compounding effects could lead to decreased product availability and increases in operational overhead. The objective explanation to understand the underlining concern of the Departments is incomplete and this attempt to create "Checks and balances" shifts the responsibility from the department of health over to the individual entities without addressing any particular concerns. This proposed revisions sends a message of lack of integrity and accuracy which if these concerns have merits there are mechanisms built in 1171.24 that can be used to address such matters.

PROPOSED: § 1171a.31. Test results and reporting

- This proposed subsection (c) provides the procedure for a sample that fails testing. This proposed subsection allows a failed sample to be re-tested by the same laboratory. If the initially failed sample were then to pass re-testing, proposed subsection (c)(2) requires a different laboratory to confirm that passing test. Proposed subsection (c)(3) allows the Department to opt to reject the confirming result from the approved laboratory.

The DOH has not adequately addressed re-testing procedures for qualified materials. These revisions do not address a clear path to "re-testing", the consequences of which create a bottleneck of qualified products that successfully pass multiple retests, but are still prohibited from reaching the patient population.

What would be the basis for the DOH rejecting the ability to sell product that has successfully passed retesting procedures?

The mandatory reporting of internal R&D Test Results proposed in §1171a.35(b)(1) creates cause for concerns over protection of intellectual property.

PROPOSED: § 1151a.34. Packaging and labeling of medical marijuana products

- Requiring that labels be firmly affixed to the container directly holding medical marijuana as well as outer packaging

Packaging shape and sizes and the amount of information required to be the labels prohibit the ability to achieve this objective. If possible consider a slimmed down label that can be affixed to the container.

Sincerely,

On Behalf of FarmaceuticalRX.

Josh Rakes
Director of Compliance