Ohio Medical Marijuana Control Program

Executive Summary: Recall of One Orijin Rosin Product
March 9, 2020

I. Introduction

The Ohio Medical Marijuana Control Program (MMCP) is administered by three state agencies: State of Ohio Board of Pharmacy (Pharmacy Board), the Ohio Department of Commerce (Commerce), and the Ohio State Medical Board (Medical Board). One Orijin, located in Columbus, Ohio, is licensed as a processor by the Ohio Department of Commerce. On Nov. 15, 2019**,** the MMCP issued a mandatory recall for product manufactured by One Orijin. This recall notified the public that the product was manufactured using a non-compliant process and placed an administrative hold on the product, which prevents the product from being transferred to dispensaries.

II. Background

The Pharmacy Board is responsible for the licensing and regulation of dispensaries, and the registration of patients and caregivers. Commerce is responsible for the licensing and regulation of cultivators, processors and testing laboratories. One Orijin is licensed to manufacture and sell medical marijuana products to dispensaries.

Licensed processors manufacture medical marijuana products. The Department divides processors into three categories: standalone, vertically integrated, and a plant-only processor[1], which is a cultivator that distributes plant material directly to dispensaries. One Orijin is licensed as a "stand alone processor."

Licensed cultivators grow medical marijuana and are required to track the inventory in MMCP's seed-to-sale system, Metrc. This system tracks the medical marijuana product as it grows, is tested, and potentially manufactured. The plant material is required to be tested after its harvest but before it is transferred to a processor or dispensary. After the required testing is performed, the plant material can then be transferred to a processor for manufacturing or sold to a dispensary.

If the plant material is intended to be utilized in the manufacturing of medical marijuana products, O.A.C. 3796:2-2-06(B) requires a testing laboratory to test every plant material sample for the following:

(1) Pesticide and fertilizer residue;

(2) Moisture content;

(3) Foreign matter contamination; and

[1] A plant-only processor is a cultivator that distributes plant material directly to a dispensary pursuant as defined in O.A.C. 3796:1-1-01(A)(38).

(4) Cannabinoid potency, including, at a minimum, the following:

(a) Delta-9-tetrahydrocannabinolic acid (THCA);

(b) Delta-9-tetrahydrocannabinol (THC);

(c) Cannabidiolic acid (CBDA); and

(d) Cannabidiol (CBD)

Cultivators may submit the plant material for additional testing. This testing may exceed the minimum testing requirements found in O.A.C. 3796:2-2-06(B). If a cultivator submits plant material for microbial testing and results identify that microbial contamination exceeds the permitted thresholds, the cultivator shall not sell the product as plant material to dispensaries. However, the cultivator is permitted to transfer the product to a processor to be utilized in the manufacture of medical marijuana products, as long as a compliant remediation method is used. O.A.C. 3796:4-2-04(f) states "if a batch of plant material is not deemed to have passed testing for microbial contamination, that batch may be designated for extraction by hydrocarbon-based or carbon dioxide-based methods."

Finally, pursuant to O.A.C. 3796:3-2-06, all manufactured products in their final form must have all required testing performed prior to packaging for distribution to a dispensary.

III. One Orijin Recall

On Nov. 15, 2019, a Pharmacy Board Agent contacted a Commerce Compliance Agent regarding an issue with a strain name. While reviewing the strain name, the Compliance Agent discovered the product was manufactured with plant material that tested positive for microbial contamination. By rule, this means the processor would have been permitted to manufacture marijuana products utilizing one of the two permitted extraction methods, hydrocarbon-based extraction or carbon dioxide-based extraction. The product identified was a rosin, which was extracted from the plant material by lightly heating the material and utilizing a mechanical press. This method is not currently permitted under O.A.C. for use with plant material that fails testing for microbial contamination. However, the finished product did pass all required laboratory testing, including testing for microbial contamination. The product was packaged in a circular jar and the appearance is similar to the consistency of tree sap.

As a result of the discovery and confirmation by the Compliance Agent, a communication detailing the circumstances of the product non-compliance was sent to all patients on Nov. 15, 2019. The product was placed on administrative hold in Metrc, which prevents the product from being transferred to another licensed facility. This means One Orijin was no longer able to transfer the product to a dispensary for sale. On Nov. 17, 2019, a second communication was sent to patients providing additional details on the product names.

To understand the potential impact to product safety, the MMCP required One Orijin to submit the product for additional testing. The testing was performed on unsold product returned by the dispensary to the processor, One Orijin. The following provides a summary of the testing activity.

- 22 samples were sent to North Coast Testing Laboratory. This sample represents 136 units of rosin product.
- North Coast Testing Laboratory began testing on Feb. 19, 2020
- North Coast Testing Laboratory reported results on Feb. 21, 2020.
- All samples passed additional testing for microbial contaminants.

The MMCP performed the following actions as a result of the product recall and administrative hold:

- Identified all products located at the processor and dispensaries that were affected by the recall.
- Communicated to patients that recalled products may be returned to dispensaries.
- Required One Orijin to collect all unsold products located at dispensaries.
- Required One Orijin to submit to additional testing.
- Any product returned by a patient was destroyed at the returned dispensary location.
- Identified a new Metrc process that will require licensees to identify plant material that fails microbial testing requires remediation and then identify the compliant method utilized.

One Orijin performed the following actions related to the product recall:

- Suspended manufacturing of the rosin product temporarily.
- Updated its Standard Operating Procedures (SOP). This includes now requiring only plant material that has passed all required testing in the manufacturing of rosin, improved record keeping techniques for the extraction process, and created a new role that will monitor compliance with inventory, regulatory, and SOP management.
- Required continued education for all employees.

IV. Administrative Hold and Recall Metrics

<u>Products Recalled:</u>

- Pineapple Express
- Blue Boi Z7
- Afghani #1

Product I.D.[2] Recalled:

- M00000038808: Sol Vap 62.3 - 12.6 - 5
- M00000039812: Sol Vap 59.8 - 0.025 - 5
- M00000036317: Sol Vap 45.85 - 47.44 - 10
- M00000036932: Sol Vap 48.79 - 50.59 - 10
- M00000037232: Sol Vap 68.8 - 0.18 - 5
- M00000038319: Sol Vap 40.7 - 46.8 – 10

Product and Dispensary Metrics:

- Product impacted: 2,214 retail units delivered to dispensaries
- Number of patients that purchased product:488
- Number of dispensations of product: 584
- Number of dispensaries impacted by recall: 29

Patient Adverse Events:

- One adverse event was received by the Pharmacy Board. No additional follow-up was identified.
- One Orijin received no patient health complaints.

V. Conclusion

The MMCP recall process, which currently includes the subsequent additional testing of the recalled product, did not identify any safety or health concerns for patients that may have purchased and used the rosin.

Although the recalled product passed lab testing and there were no actionable health concerns identified, the MMCP has begun implementation of a new Metrc process that will require licensees to identify plant material that fails microbial testing and therefore requires remediation. A processor utilizing plant material that requires remediation must identify the method of remediation used, with options being limited to compliant methods. Full testing is still required on the final manufactured product, but this will reduce future compliance issues related to the circumstances of the recall.

[2] All medical marijuana products must have an assigned Product ID to be accepted by a dispensary and to enable submission of dispensation data to the Ohio Automated Rx Reporting System. This applies to each medical marijuana strain and medical marijuana form and dose. The assignment of a Product ID is to ensure that only products in compliance with MMCP regulations are available to patients and their caregivers.