EXECUTIVE SUMMARY:
Recall of Certified Cultivators, LLC Certified Live Resin Southside Legend Vape Carts
February 15, 2022

I. Introduction

The Ohio Medical Marijuana Control Program (MMCP) is administered by three state agencies: the State of Ohio Board of Pharmacy (Pharmacy Board), the Ohio Department of Commerce (Commerce), and the Ohio State Medical Board (Medical Board). Certified Cultivators, LLC (Certified Cultivators), located in Dayton, Ohio, is licensed as a level one cultivator and processor by the Ohio Department of Commerce. On October 13, 2021, the MMCP issued a mandatory recall[1] for product manufactured by Certified Cultivators. This recall notified the public that the product did not receive the full battery of required testing prior to being sold at dispensaries. The recalled products were not tested for heavy metals, pesticides, residual solvents, or mycotoxins. The MMCP placed an administrative hold on and quarantined the product, preventing it from being sold to patients.

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. Certified Cultivators holds both a cultivator and processor license to grow, manufacture, and sell medical marijuana products to dispensaries.

Licensed cultivators grow medical marijuana and are required to track the inventory in MMCP's seed-to-sale inventory tracking 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 it is harvested but before it is transferred to a processor or dispensary. After the required testing is performed and the plant material passes the required analysis, it can then be transferred to a processor for manufacturing or sold to a dispensary.

Licensed processors manufacture medical marijuana products and are also required to track their inventory in Metrc. Once a processor extracts medical marijuana, it may have laboratory testing conducted on the medical marijuana extract pursuant to O.A.C. 3796:4-2-04(D), which requires the extract to be tested for the following:

(a) Pesticide and fertilizer residue; and

(b) Cannabinoid potency including, at minimum:

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

[1] See Attachment A

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

(iii) Cannabidiolic acid (CBDA);

(iv) Cannabidiol (CBD); and

(v) Cannabinol (CBN);

(c) Mycotoxin contamination;

(d) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury; and

(e) Residual solvents.

Once the extract is used in the manufacturing of a medical marijuana product, O.A.C. 3796:4-2-04(C) requires the product to be tested for all of the following prior to packaging for distribution to a dispensary:

(1) Cannabinoid potency including, at minimum:

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

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

(c) Cannabidiolic acid (CBDA);

(d) Cannabidiol (CBD); and

(e) Cannabinol (CBN);

(2) Foreign matter contamination;

(3) Microbial contamination;

(4) Mycotoxin contamination, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for mycotoxin contamination by a licensed testing laboratory;

(5) Heavy metal contamination including, at a minimum, arsenic, cadmium, lead, and mercury, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for heavy metal contamination by a licensed testing laboratory;

(6) Pesticide and fertilizer residue, if a medical marijuana extract was used in the manufacture of the product that was not previously tested for pesticide or fertilizer residue contamination by a licensed testing laboratory; and

(7) Residual solvents, if a hydrocarbon-based medical marijuana extract was used in the manufacture of the product that was not previously tested for residual solvent contamination by a licensed testing laboratory.

Certified Cultivators did not test the medical marijuana extract that was used to manufacture the products subject to this recall pursuant to O.A.C. 3796:4-2-04(D). Therefore, testing on the manufactured product intended to be distributed to a dispensary should have included analysis for mycotoxins, heavy metals, pesticide and fertilizer residue, and residual solvents as required by O.A.C. 3796:4-2-04(C)(4) through (7). Certified Cultivators failed to complete that required testing on these products prior to distributing them to dispensaries.

III. Recall

On October 13, 2021, the MMCP received an anonymous email that there were Certified Cultivators products being sold that were not tested for all contaminants required by rules. After further investigation by the MMCP and speaking with Certified Cultivators representatives, it was determined that some products were not fully tested pursuant to O.A.C. 3796:4-2-04(C).

The Department of Commerce MMCP, in coordination with the Ohio Board of Pharmacy, on October 13th issued a mandatory recall on the affected products, placed an administrative hold on the products at the processor, and quarantined the products at the dispensary so they could not be sold to patients.

The MMCP directed Certified Cultivators to pick up products from the affected dispensaries so they could be randomly tested. On October 27th, the licensee began picking up the products. On November 2nd, North Coast Testing Laboratory randomly selected 10 units of the recall product for testing. The lab reported on November 5th that the products passed all required testing.

On November 19th, the MMCP announced that the products were retested and determined to be safe for patients.

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
- Communicated product recall updates, including testing results, to patients
- Required Certified Cultivators to collect all unsold products located at dispensaries
- Required Certified Cultivators to submit to additional testing
- Required product returned by patients to be destroyed at the return dispensary location
- Determined that there were violations of Chapter 3796 of the Administrative Code based on the above that were resolved via a Consent Agreement

Certified Cultivators, LLC performed the following actions related to the product recall:

- Cooperated with the MMCP investigation into the matter and responded to all requests from the Department
- Entered into a Consent Agreement with the Department to resolve the recall
- Submitted to additional testing required by the Department
- Conducted an internal audit
- Conducted enhanced training for employees
- Added an additional internal check to confirm all test results
- Updated its Standard Operation Procedures (SOP)

IV. Recall Metrics

Products Recalled

- Certified Live Resin Southside Legend

Product IDs[2] Recalled

- M00000224907: Oil Vap 7-0-50 CERTIFIED LIVE RESIN SOUTHSIDE LEGEND

Product and Dispensary Metrics

- Retail units delivered to dispensaries: 888
- Number of patients that purchased product: 183
- Number of units dispensed to patients: 231
- Returns: 64
- Number of dispensaries impacted by recall: 20

Patient Adverse Events

- No reports of adverse events were received.

V. Conclusion

The MMCP suspended sales of all Certified Resin Southside Legend vape carts to investigate testing not conducted on the product. The sample units of the product subsequently passed required testing for contaminants and the MMCP did not identify any safety or health concerns for patients who may have purchased and used the product.

The MMCP is committed to ensuring patients have access to safe products and will continue to identify program improvements, including information gleaned from this recall and investigation, to inform any future regulatory and policy updates and ensure facilities are operating appropriately.

[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.

ATTACHMENT A

OHIO MEDICAL MARIJUANA CONTROL PROGRAM
MANDATORY PRODUCT RECALL - 10/13/21

TOPIC: Mandatory Product Recall

ISSUE: The Ohio Medical Marijuana Control Program (MMCP) is issuing a mandatory product recall on manufactured products sold to dispensaries by processor, Certified Cultivators, LLC. This recall is being initiated by the MMCP because the manufactured products did not receive the full battery of required testing prior to being sold at dispensaries. The recalled products were not tested for heavy metals, pesticides, residual solvents, and mycotoxins. The MMCP is investigating this matter and will issue an executive summary at the conclusion of the investigation.

AFFECTED PRODUCT:

Product Name: Certified Live Resin Southside Legend

Purchase Dates: Beginning September 1, 2021 - Present

Processor Name: Certified Cultivators, LLC

Product ID:
M00000224907: Oil Vap 7 - 0 - 50 CERTIFIED LIVE RESIN SOUTHSIDE LEGEND

Purchased from the following dispensaries:

About Wellness - Lebanon
Bloom Medicinals - Akron
Bloom Medicinals - Columbus
Bloom Medicinals - Painesville
Bloom Medicinals - Seven Mile
Columbia Care - Dayton
Columbia Care - Logan
Columbia Care - Marietta
Columbia Care - Monroe
Strawberry Fields - Columbus
Sunnyside - Cincinnati
Sunnyside - Marion

Terrasana - Columbus
Terrasana - Garfield Heights
Verdant Creations - Columbus
Verilife - Cincinnati
Verilife - Hillsboro
Verilife - Wapakoneta
Zen Leaf - Cincinnati
Zen Leaf - Dayton

No reports of adverse reactions for this product have been reported to the MMCP at this time.

Patients who have purchased the recalled product should stop using it. *All unused product should be returned to the dispensary where purchased. Returned products will not count toward a patient's 90-day possession limit. For more information on returns, please contact the dispensary where the product was purchased.*

Anyone who thinks that they may be experiencing serious or life-threatening issues should seek immediate medical attention. Patients are reminded that any adverse reactions should be reported to the MMCP toll-free helpline (1-833-464-6627).