BEFORE THE ADMINISTRATIVE HEARING COMMISSION STATE OF MISSOURI

DELTA EXTRACTION, LLC)
Petitioner,)
VS.) Case No. 23-0608
MO DEPARTMENT OF HEALTH)
AND SENIOR SERVICES, et al.,)
Respondents.)

AMENDED COMPLAINT

Petitioner Delta Extraction, LLC ("Delta") appeals the August 2, 2023 final decision of the Respondents Department of Health and Senior Services ("DHSS") and Division of Cannabis Regulation ("DCR") that Petitioner must immediately suspend operations. Delta also appeals Respondents' August 3, 2023 final decision to place on administrative hold Delta's products, and Respondents' August 14, 2023 decision and issuance of a recall of tens of thousands of Delta's products. Respondents' decisions should be overturned, and Petitioner should be allowed to re-start its operations and the recall should be revoked.

PARTIES

- 1. Petitioner Delta Extraction is a Missouri limited liability company organized under the laws of Missouri.
- 2. Delta is a marijuana infused products manufacturer possessing license number MAN00022 granted by the Missouri Department of Health and Senior Services.

EXHIBIT B

HB: 4894-4949-9261.1

- 3. Respondent DHSS is a state agency created by statute. DHSS is charged with licensure and regulation of marijuana infused products manufacturers.
- 4. Respondent Division of Cannabis Regulation is a division within DHSS responsible for regulating the adult use of cannabis.

JURISDICTION

- 5. A marijuana infused products manufacturer license holder "may seek review" of DHSS's decision to impose penalties. 19 CSR-100.1.020(4)(A).
 - 6. Petitioner timely filed this complaint. 19 CSR-100.1.020(4)(B).
 - 7. This Commission has jurisdiction over this matter. 19 CSR-100.1.020(4).

BACKGROUND

- 8. On August 2, 2023, Delta received a letter from DHSS ordering the immediate suspension of Delta Extraction's operations. A true and correct copy of that letter is attached as Exhibit A.
- 9. That letter states that the Division of Cannabis Regulation ("DCR") has determined:
 - a. "A credible report, through allegations supported by data from the statewide track and trace system (Metrc) of inversion of marijuana product at the licensed facility"; and
 - b. "A credible report, through data from the statewide track and trace system(Metrc) which demonstrates that the Licensee is permitting marijuana

product to enter the regulated market without being compliantly tested." Ex. A.

- 10. Due to these two vague reasons, DHSS and/or DCR ordered Delta Extraction to cease all operations at 5:00 p.m. on August 2, 2023. See Ex. A.
 - 11. The letter also serves as a "notice of investigation." Ex. A.
- 12. The letter also stated that DCR was placing on administrative hold "all marijuana in the facility or originating from [Delta]." Ex. A.
- 13. Delta Extraction was advised that DHSS's letter is a final decision, appealable to the Administrative Hearing Commission. Ex. A.
- 14. Despite the Order of Immediate Suspension's placement of Delta's products on administrative hold, DCR issued a separate Notice of Administrative Hold (the "Hold Notice") on August 3, 2023. A true and correct copy of that communication is attached as Exhibit B.
- 15. The Hold Notice said that "[m]arijuana product in [Delta's] inventory has been placed on administrative hold" and that DCR had determined there was a "credible and imminent threat to public health that warrants placing product" within Delta's inventory and at other licensed facilities on administrative hold. Ex. B.
- 16. On August 14, 2023, DCR issued a Notice of Recall (the "Recall Notice") of all of Delta's products. A true and correct copy of the Recall Notice is attached as Exhibit C.

- 17. The Recall Notice said that the DCR may issue a recall notice where marijuana product "presents a potential threat to health and safety." Ex. C.
- 18. The Recall Notice stated that such products "were not compliantly tracked in the statewide track and trace system (METRC) in order for DCR to verify the products came from marijuana grown in Missouri or that the product passed required testing prior to being sold at dispensaries." Ex. C.
- 19. On its website, DCR uploaded a list of all Delta products recalled.

 Approximately 62,800 SKUs of Delta products were included on the recall list.¹

APPEAL

- 20. Delta appeals Respondents' determination that there is a "credible and imminent threat to public health that warrants immediate suspension of the license." Ex. A.
- 21. Delta further appeals DHSS' order that Delta Extraction immediately suspend operations. See Ex. A.
- 22. Delta appeals Respondents' determination that there is a "credible and imminent threat to public health that warrants placing product within [Delta's] inventory on administrative hold." Exs. A, B.

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¹ https://health.mo.gov/safety/cannabis/xls/product-recall-list081423.xlsx

- 23. Delta appeals Respondents' determination that its marijuana products "present[] a potential threat to health and safety" that warrants a recall of 62,800 SKUs of Delta's products. Ex. C.
- 24. Delta Extraction also appeals Respondents' Recall Notice, recalling 62,800 SKUs of Delta's products. Ex. C.
- 25. Delta challenges the constitutionality and validity of 19 CSR 100-1.020(3)(G) on the basis that it (1) is not authorized by Art. XIV of the Missouri Constitution, and (2) permits Respondents to revoke Petitioner's marijuana infused products manufacturer license without undergoing any of the procedural requirements contained in § 621.045, RSMo.
- 26. Delta also challenges the constitutionality of the Respondents' application of DCR's Regulations and of Art. XIV of the Missouri Constitution to Delta Extraction, in that their application of such violates the Due Process Clause of the United States Constitution and Missouri Constitution and the Takings Clause of the United States Constitution and the Missouri Constitution.

WHEREFORE, Petitioner hereby appeals Respondents' decision to suspend its license and order that it immediately cease operations and requests that this Commission conduct a hearing in this matter and issue an Order directing Respondents to remove the suspension of Petitioner's license, to remove the administrative hold placed on all of Petitioner's products, to revoke the product recall regarding 62,800 SKUs of Petitioner's

products, and to allow Petitioner to begin operations. Petitioner requests such other and additional relief as the Commission deems just and proper.

Dated: September 1, 2023

HUSCH BLACKWELL LLP

By: /s/ Lowell D. Pearson

Lowell D. Pearson, No. 46217 Alexa B. Barton, No. 71779 235 East High Street, Suite 200 P. O. Box 1251 Jefferson City, MO 65102

Phone: (573) 635-9118 Fax: (573) 634-7854

lowell.pearson@huschblackwell.com allee.barton@huschblackwell.com

STINSON LLP

By: /s/ Charles W. Hatfield

Charles W. Hatfield, No. 40363 Alixandra S. Cossette, No. 68114 Alexander C. Barrett, No. 68695 230 W. McCarty Street

Jefferson City, MO 65101 Phone: (573) 636-6263

Fax: (573) 636-6231

chuck.hatfield@stinson.com alixandra.cossette@stinson.com alexander.barrett@stinson.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was filed via this Administrative Hearing Commission's electronic filing system on this 1st day of September, 2023, and emailed to the following:

Joshua E. Douglass Mickes O'Toole, LLC 117 W. 20th Street, Suite 201 Kansas City, MO 64108 jdouglass@mickesotoole.com

Attorneys for Respondent Missouri Department of Health and Senior Services

/s/ Lowell D. Pearson Attorney for Petitioner



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 | Phone: 573-751-6400 | FAX: 573-751-6010 RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711



Paula F. Nickelson Director Michael L. Parson Governor

ORDER OF IMMEDIATE SUSPENSION

August 2, 2023

Delta Extraction, LLC, MAN000022 Ms. Rachael Herndon 5281 Willow Ford Rd Robertsville. MO 63072

Subject: Order of Immediate Suspension

Dear Ms. Herndon,

Pursuant to Article XIV Section 2 4.(1)(a) and 19 CSR 100-1.020(3), the Department of Health and Senior Services may immediately suspend all or part of the operations of a marijuana facility where there is a credible and imminent threat to public health or public safety.

Pursuant to 19 CSR 100-1.020(3)(A)4 and 19 CSR 100-1.020(3)(G)1, the Division of Cannabis Regulation (DCR), Section for Compliance and Enforcement is issuing Delta Extraction, LLC, MAN000022 an *Order of Immediate Suspension*.

DCR has determined there is a credible and imminent threat to public health that warrants immediate suspension of the license. Specifically:

- 1. A credible report, through allegations supported by data from the statewide track and trace system (Metrc) of inversion of marijuana product at the licensed facility.
- 2. A credible report, through data from the statewide track and trace system (Metrc) which demonstrates that the Licensee is permitting marijuana product to enter the regulated market without being compliantly tested.

Therefore, DCR ORDERS the Licensee to immediately suspend operations as follows:

- The Licensee shall immediately stop all operations and activities, including off-site operations and
 activities related to the Licensee, such as seed-to-sale system and statewide track and trace system
 (Metrc) entries.
- No marijuana product shall be moved or altered in any way, including physically or in the statewide track and trace system (Metrc). All marijuana in the facility or originating from the Licensee will be placed on administrative hold in Metrc by DCR.
- The Licensee shall secure all marijuana product in the facility immediately such as moving all marijuana product to the vault or storage area.
- The Licensee shall secure the facility and shall not allow any personnel, including owners or security guards, to enter the facility.
- The Licensee shall immediately work with DCR, through their compliance officer, to reestablish remote access of the Licensee's electronic video monitoring system. Pursuant to 19 CSR 100-1.020(3)(A)2, DCR

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will begin to assess the Licensee fines for each day the Licensee is in violation of 19 CSR 100-1.090(1)(C)2.

The Licensee shall follow standard operating procedures pursuant to 19 CSR 100-1.100(4)(J) to cease operations.

This order also serves as notice of investigation pursuant to 19 CSR 100-1.030(2)(B)5. Until the Licensee receives written notice from DCR that the investigation is concluded, the Licensee must preserve all records of any type related to the subject of this investigation, including all video camera recordings and facility access controls records. The Licensee is to notify DCR in writing at CannabisComplaints@health.mo.gov, prior to 5pm CST today, that all records have been preserved, the means in which the records have been preserved, and the location of these records.

Pursuant to 19 CSR 100-1.030(2)(C), licensees "must cooperate in any investigation conducted by the Department." Failure to cooperate with a Department investigation may be grounds for penalties, including fines, suspension, or revocation of the license.

The Licensee must immediately, but prior to 5pm CST today, reply in writing to DCR at CannabisComplaints@health.mo.gov indicating the following:

- 1. That the order has been received and that the licensee intends to comply.
- 2. Verify that all operations for the Licensee has ceased and all personnel have been removed from the facility, with except to staff designated by DCR.
- 3. Verify personnel will not have access to the facility and/or will not complete any activities related to the Licensee, including seed-to-sale system and statewide track and trace system (Metrc) entries. The Licensee shall remove access privileges for all employees and provide verification that access privileges have been removed. The Licensee shall provide a daily electronic log of controlled entry for the facility to DCR at CannabisComplaints@health.mo.gov by 9am CST for the previous day until the Licensee receives written notice from DCR.
- 4. Verify that the Department will have access to the facility, including records, at any time including the availability of the designated contact or an employee who has the knowledge and ability to access all areas of the facility or records.
- 5. Understand that all Department approvals during suspension will be provided in writing.

DCR will schedule a conference call with the Licensee to further advise the Licensee of the nature of the investigation and this order within forty-eight (48) hours of issuing the Order.

During the suspension, the Licensee must maintain compliance with all applicable requirements outlined within 19 CSR 100-1, for example, facility security, such as electronic video monitoring and access control requirements. In addition, no personnel shall enter the facility without DCR written approval.

Pursuant to 19 CSR 100-1.020(4), the Licensee may appeal this decision by filing a petition with the Missouri Administrative Hearing Commission within thirty (30) days of the date this decision is sent, which is the date stated above.

For questions or additional information regarding this order, please reach out to DCR at CannabisComplaints@health.mo.gov.

Andrea Balkenbush, Deputy Director

Division of Cannabis Regulation
Department of Health and Senior Services

cc: Joshua Stockman, Bureau of Investigation & Enforcement, Manager
Kourtney Blomberg, Investigation Supervisor
Chelsea Gibbs, Investigation Supervisor
Sarah Burch, Bureau of Business Licensing Services, Manager
Bruce Dooley, Facility Compliance Manager
Brittany Kirkweg, Section for Compliance & Enforcement, Deputy Director
Amy Moore, Division of Cannabis Regulation, Director

From: DHSS.DCR-Complaints < CannabisComplaints@health.mo.gov >

Subject: Notice of Administrative Hold Date: August 3, 2023 at 4:37:30 PM CDT

To: DHSS.DCR-Complaints < CannabisComplaints@health.mo.gov

Dear Licensee,

Marijuana product in your inventory has been placed on administrative hold. Pursuant to 19 CSR 100-1.100(4)(P), the Department of Health and Senior Services may immediately place marijuana product on administrative hold where the product presents a potential threat to health and safety. Product must remain on administrative hold until such time as the Department determines the product is safe, may be remediated, or must be destroyed.

Per 19 CSR 100-1.010(2), administrative hold means a status given to marijuana product by the Department that prohibits any activity with the marijuana product including waste, sale, or transfer of the marijuana product until the hold is lifted.

Per 19 CSR 100-1.180(2)(B)2, prior to sale, delivery, or distribution, dispensary licensees shall verify through the statewide track and trace system that marijuana product has not been placed on administrative hold, recalled, or otherwise required to be destroyed. It is important for licensees to understand that seed-to-sale systems may not have the functionality to notify a licensee that marijuana product is on administrative hold and it is the licensee's responsibility to verify this information through the statewide track and trace system (Metrc) prior to sale, delivery, or distribution.

As part of an on-going investigation, DCR has determined there is a credible and imminent threat to public health that warrants placing product within this Licensee's inventory on administrative hold.

Therefore, DCR reminds/requires the Licensee to take the following actions in addition to rule requirements stated in this notice:

- The Licensee shall immediately place all product that is on administrative hold in quarantine in the space previously designated for quarantine items and within a secure space with limited access.
- No marijuana product on administrative hold shall be moved or altered in any way once it has been secured in quarantine, including wasted.

Pursuant to 19 CSR 100-1.030(2)(C), licensees "must cooperate in any investigation conducted by the department." Failure to cooperate with a Department investigation may be grounds for penalties, including fines, suspension, or revocation of the license or certification.

The designated contact must immediately, <u>but prior to 10am CST tomorrow</u>, <u>August 4</u>, <u>2023</u>, reply to this notice indicating the following:

- 1. That the notice of administrative hold has been received and that the licensee intends to comply; and
- 2. Explain how the Licensee will ensure all marijuana product on administrative hold has been moved to quarantine and made secure and that no action, including wasting will occur with packages on administrative hold; and
- 3. Verification that SOPs outline verification that marijuana product is not on administrative hold prior to sale, delivery or distribution and that staff have been trained and are following this requirement.

DCR will be in further contact as the investigation proceeds. We appreciate your patience as we work through this process. For responses to this notice, questions or additional information regarding this notice, please respond to DCR at cannabiscomplaints@health.mo.gov.

Andrea Balkenbush, Deputy Director
Division of Cannabis Regulation
Department of Health and Senior Services

CONFIDENTIALITY STATEMENT

This electronic communication is from the Division of Cannabis Regulation and is confidential, privileged and intended only for the use of the recipient named above. If you are not the intended recipient or the employee or agent responsible for delivering this information to the intended recipient, unauthorized disclosure, copying, distribution or use of the contents of this transmission is strictly prohibited. If you have received this message in error, please notify the sender immediately at the following email address CannabisComplaints@health.mo.gov or by calling 866-219-0165. Thank you.



Missouri Department of Health and Senior Services

P.O. Box 570, Jefferson City, MO 65102-0570 | Phone: 573-751-6400 | FAX: 573-751-6010 RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711



Paula F. Nickelson Director Michael L. Parson Governor

DIVISION OF CANNABIS REGULATION NOTICE OF RECALL

August 14, 2023

Topic: Notice of Mandatory Recall

Issue: The Missouri Division of Cannabis Regulation (DCR) is issuing a patient and consumer communication to alert patients and consumers about a mandatory product recall. Pursuant to 19 CSR 100-1.100(4)(P), the DCR may issue a public notice of recall where marijuana product presents a potential threat to health and safety.

DCR is issuing a product recall on manufactured products sold to dispensaries and manufacturers by infused product manufacturer, Delta Extraction, LLC, MAN000022. The recalled products were not compliantly tracked in the statewide track and trace system (METRC) in order for DCR to verify the products came from marijuana grown in Missouri or that the product passed required testing prior to being sold at dispensaries.

Affected Products: The list of recalled products is located at here.

No adverse reactions for this product have been reported to the DCR at this time.

Patients and consumers who have purchased the recalled product should discontinue use. . All unused product(s) should be discarded or returned to the dispensary where purchased. Returned products will not count toward a patient's purchase limit. For more information on returns, please contact the dispensary where the product was purchased. For information on recalled items, please go to DCR's website here.

Anyone who thinks that they may be experiencing adverse reactions should seek immediate medical attention. Patients and consumers are reminded that any adverse reactions should be reported to CannabisComplaints@health.mo.gov or fill out a complaint form located here.

Andrea Balkenbush, Deputy Director Division of Cannabis Regulation Department of Health and Senior Services

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Thank you

Your electronic document has been successfully submitted.

Document Name

Amended Complaint; Exhibit A; Exhibit B; Exhibit C

Case Number

23-0608

Date Submitted

9/1/2023 2:23 PM