

GRETCHEN WHITMER
GOVERNOR

STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

January 31, 2020

Compliance Action - Citation

Palmatier Enterprises, Inc., Assumed Name The Spott

ERG No.: 000175

License No.: SC-000002

CMP No.: 19-000083 & 19-000735 ENF No.:19-00049 & 19-00062

Following an investigation, the Marijuana Regulatory Agency (MRA) determined that Palmatier Enterprises, Inc., Assumed Name The Spott ("Respondent"), license no. SC-000002, violated the Medical Marihuana Facilities Licensing Act (MMFLA), and/or administrative rules promulgated thereunder as follows:

1. ENF No. 19-00049

a. On July 12, 2019, a licensed grower ("Complainant") submitted a complaint to the MRA about the validity of microbial results received from Respondent on marijuana product (flower). Complainant packaged the same flower into two packages, tag nos. 1A4050100001D4D000000096 (package tag #0096) 1A4050100001D4D000000093 (package tag #0093). Package tag #0096's initial results indicated BTGN at 2800 CFU/g, TC at 2200 CFU/g, and TYM at 14250 CFU/g; these results exceed the MRA's published action limit, and thus are failing results. Package tag #0093's initial results indicated BTGN at ND (not detected), TC at ND, and TYM at 2300 CFU/g; these results did not exceed the MRA's published action limit, and thus are passing results. The failures from package tag #0096 contained bacteria failures (microbes); package tag #0093's results did not detect bacteria. Although it is possible to have a failing and passing result on the same flower, typically, detection from the additional microbes would been seen. Therefore, the MRA questioned the validity of these results. At the MRA's request, Respondent analyzed its field duplicates for both samples. Package tag #0096's field duplicate analysis results indicated BTGN at ND, TC at ND, and TYM at 650 CFU/g; and, package tag #0093's field duplicate analysis results indicated BTGN at ND, TC at ND, and TYM at 1050 CFU/g. The original results and the field duplicate results did not correlate. Therefore, Respondent failed to use analytical testing methodologies that produced scientifically accurate results.



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b. Based on the above, Respondent's analytical testing methodologies for the required safety tests do not produce scientifically accurate results for each test it conducts in violation of Mich Admin Code, R 333.247(1)(b).

2. ENF No. 19-00062

- a. On August 1, 2019, Respondent retested MKX Blue Raz Cart, MKX Forbidden Fruit Cart, and MKX Strawberry Lemonade Cart which are marihuana products intended for inhalation; this marihuana product is where the marihuana concentrate has been placed into the inhalation device. This is the form that it is in when available for sale, i.e., a marihuana product that is in a final package.
- b. MKX Blue Raz Cart, METRC source tag number 1A405010000170D0000000068 (source tag #0068) had initial compliance testing by another licensee on July 16, 2019; the sample tag number for the initial compliance testing was 1A405010000170D000000111; failing results were uploaded to METRC on July 24, 2019.
- c. On August 1, 2019, Respondent sampled source tag #0068; the sample tag numbers were 1A405010000170D000000414 and 1A405010000170D000000415. On August 8, 2019, Respondent uploaded failing test results in METRC.
- d. MKX Forbidden Fruit, METRC source tag number 1A405010000170D0000000070 (source tag #0070); and MKX Strawberry Lemonade Cart, METRC source tag A405010000170D000000077 (source tag #0077) had initial compliance testing by another licensee on July 25, 2019.
- e. On August 1, 2019, Respondent sampled source tag #0070; the sample tag numbers were 1A405010000170D000000416 and 1A405010000170D000000417. On August 8, 2019, Respondent uploaded failing test results in METRC.
- f. On August 1, 2019, Respondent sampled source tag #0077 were sampled for retesting; the sample tag numbers were 1A405010000170D000000418 and 1A405010000170D000000419. On August 8, 2019, Respondent uploaded failing test results in METRC.
- g. Based on the above actions after August 1, 2019, Respondent retested marihuana product that was in its final package, in violation of Mich Admin Code, R 333.246(3)(a).

Mich Admin Code, R 333.219 provides that a licensee found in violation of the MMFLA and/or administrative rules may be subject to sanctions, including fines. For the above violations, the MRA intends to impose a fine of \$4,000.00.

If you agree to resolve this citation as set forth in the citation agreement below, you must sign and return the attached citation agreement within 30 days after receipt of the citation. The fine must be paid within 30 days after you receive the citation agreement signed by the enforcement director. Return the signed agreement and submit payment by:



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STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS LANSING

ORLENE HAWKS DIRECTOR

Mailing to:

Department of Licensing & Regulatory Affairs Marijuana Regulatory Agency P.O. Box. 30205 Lansing, Michigan 48909

Appearing in Person:

Department of Licensing & Regulatory Affairs Marijuana Regulatory Agency 2407 North Grand River Lansing, Michigan 48906

Online:

You may use the online Accela Citizen Access Portal (https://aca3.accela.com/MIMM) to upload the signed citation agreement and remit payment.

Checks must be made payable to the State of Michigan and include the above enforcement (ENF) number on the memorandum line.

A citation and fully executed citation agreement may be disclosed to the public. You may submit a one-page explanation that will be placed in your license record and may be disclosed each time the citation and/or citation agreement is disclosed to the public. If no further disciplinary actions are imposed on your license within five calendar years after the citation is issued, the MRA will remove this citation from this license record.

If you fail to sign the citation agreement and timely pay the fine, the allegations in this citation will be incorporated into a formal complaint and will result in further administrative proceedings.

Continued or repeated non-compliance or repeated violations may result in further action, including the imposition of fines and/or other sanctions against your license.

Any questions about this citation should be directed to the MRA's legal section at (517) 284-8599 or MRA-LegalHearings@michigan.gov.

Dated: 31 Jan 2020

MARIJUANA REGULATORY AGENCY

Ву:

Kavita Kale, Enforcement Division Director

MARIJUANA REGULATORY AGENCY
2407 NORTH GRAND RIVER • P.O. BOX 30205 • LANSING, MICHIGAN 48909

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CITATION AGREEMENT ("Agreement")

By signing below, Respondent and the Marijuana Regulatory Agency (MRA) agree that:

- 1. This agreement is not valid or enforceable until executed by both the enforcement director and Respondent.
- 2. This agreement constitutes a full and final resolution of this citation. However, this agreement does not preclude the MRA from opening a separate investigation and pursuing appropriate disciplinary action based on information that was knowingly or unknowingly withheld by Respondent or otherwise not discovered during the initial investigation.
- 3. Respondent and the MRA agree that each has the authority to settle the citation in accordance with the terms of this agreement.
- 4. The interests of the public, the MRA, and Respondent are best served by entering into this agreement without further proceedings.
- 5. Respondent agrees to timely pay the fine set forth in the citation.
- 6. Respondent does not admit the truth of the allegations in the citation but agrees that the MRA may treat the allegations as true for purposes of resolving the citation.
- 7. The MRA reserves the right to consider this agreement in the context of subsequent disciplinary proceedings and license application or renewal decisions.

Respondent:

Palmatier Enterprises, Inc., Assumed Name The Spott License No. SC-000002

Marijuana Regulatory Agency

By: Linda Palmaties
Title: President

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By: Kavita Kale

Enforcement Division Director

Date: 03 02 2020

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ENF No. 19-00049

Respondent Explanation

1. Respondent takes issue with the following MRA assertion:

"Although it is possible to have a failing and passing result on the same flower, typically, detection from the additional microbes would be seen."

As a matter of scientific fact, microbiological contamination within a large collection of source flower material is typically very localized to one or more distinct buds, is not homogenous within the larger collection, and detection is not necessarily probable in the absence of complete homogenization of the material.

2. Respondent takes issue with the broad MRA conclusion that:

"Respondent failed to use analytical testing methodologies that produced scientifically accurate results."

While respondent welcomes an opportunity to improve testing methodology, the methodologies employed for microbiological testing are sound, based upon *Cannabis Inflorescence: Standard of Identity, Analysis, and Quality Control*, and AOAC (2019) reference methods, as required by current regulations. Respondent passed quantitative microbial proficiency tests (CM-0419) for 2019 on 05/16/2019 and for 2018 (CM-0418) on 05/21/2018.

As a result of this incident, as of 07/23/2019, respondent formally implemented complete homogenization of the entirety of sampled material prior to withdrawing sub-samples for microbiological tests to provide additional assurance that microbiological test results are consistent. (Ref: NCR-2019-019 and CAR-2019-019.)

ENF No. 19-00062

Respondent Explanation

Respondent takes issue with MRA enforcement action on this issue. At the time referenced in the citation, formal regulatory definition of "final packaging" was absent. To date, a clear definition remains absent from approved regulations, rules, and associated guidelines.

- 1. The industry-accepted definition of "Primary Packaging" is the package component that is in direct contact with the product.
- 2. The industry-accepted definition of "secondary packaging" are the package components that are presented to the customer at the point of sale that are not in direct contact with the product.

In the case of a vaporization cartridge, the vaporization device that contains the cannabis product is "primary packaging." The vaporization device is placed into secondary packaging prior to being made available for purchase.

Language in Draft Rule for Marihuana Sampling and Testing (issued for public comment on or about 1/13/2020) R 420.301 Definitions, item (h) states:

""Final package" means the form a marihuana product is in when it is available for sale by a marihuana sales location."

Respondent asserts that the vaporization cartridges that are the subject of this enforcement action were in their Primary Package, but not Final Package as defined in the Draft Rule and that this regulatory action is not warranted.