STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS[1]
MARIJUANA REGULATORY AGENCY

In the Matter of

IRON LABORATORIES, LLC
License No. SC-000003

Complaint Nos. 19-2-23,
CMP-19-000097, CMP-19-000124,
CMP-19-000128, CMP-19-000130

_____/ CONSENT ORDER AND STIPULATION

CONSENT ORDER

On August 16, 2019, the Marijuana Regulatory Agency (MRA) issued a formal complaint against the medical marijuana safety compliance facility license (no. SC-000003) of Iron Laboratories, LLC ("Respondent") under the Medical Marihuana Facilities Licensing Act (MMFLA), MCL 333.27101 *et seq.*, and rules promulgated thereunder. The complaint alleged Respondent violated Mich Admin Code, R 333.236(2); R 333.247(1), (9)(d), (14), and (16)(c); 333.248(2)(b); and 333.271(1).

Based on its investigation of the conduct alleged in the complaint, the MRA determined the safety or health of patrons or employees was jeopardized by Respondent's continued operation and that emergency action was required, as authorized under section 407(2) of the MMFLA, MCL 333.27407(2), and section 92(2) of the Administrative Procedures Act, MCL 24.292(2). Therefore, the MRA summarily suspended Respondent's license to operate a medical marijuana facility by order dated August 16, 2019.

[1] Executive Reorganization Order 2019-2 created the Marijuana Regulatory Agency (MRA) as a Type I agency within the Department of Licensing and Regulatory Affairs (LARA). MCL 333.27001(1)(a), (d). The MRA exercises its statutory powers, duties, and functions independent of LARA's direction. MCL 16.103.

The executive director reviewed the stipulation contained in this document and agrees the public interest is best served by resolution of the complaint. Therefore, the executive director finds that the allegations of fact contained in the complaint are true and that Respondent violated Mich Admin Code, R 333.236(2); R 333.247(1), (9)(d), (14), and (16)(c); 333.248(2)(b); and 333.271(1).

Accordingly, for these violations, IT IS ORDERED:

1. The order of summary suspension previously issued on August 16, 2019, is dissolved.

2. Respondent's license is suspended for a minimum of one day commencing on the effective date of this order.

3. Respondent's license automatically shall be reinstated and a renewed license shall be issued when the MRA receives and issues written approval of Respondent's updated standard operating procedures (SOPs) reflecting current, acceptable procedures and practices. This includes, but is not limited to, the following:

    a. Updated quality assurance/quality control SOPs including, but not limited to, clearly defined procedures for consistently and objectively conducting and documenting repeat testing of samples

    b. An updated SOP detailing Respondent's microbial testing method to be used beginning on the effective date of this order

4. Commencing on the effective date of this order, Respondent's license is subject to the following restrictions and conditions:

    a. Corrective Actions: Within 30 days after the effective date of this order, Respondent shall conduct a thorough audit of all internal data and data entered in the statewide monitoring system, correct all data errors and resolve all outstanding samples as directed by the MRA, issue corrected certificates of analysis (COAs) as appropriate, and document all corrective actions on a corrective action and preventative action (CAPA) form. Respondent shall email copies of all CAPA forms and all corrected COAs to MRA-Compliance@michigan.gov.

b. Accreditation Requirements: Respondent shall satisfy all requirements specified in its August 19, 2019 suspension warning letter from third-party accreditation body Perry Johnson Laboratory Accreditation, Inc. (PJLA). Respondent shall email copies of all documents and communications provided to or received by PJLA within 24 hours of submission to or receipt from PJLA to MRA-Compliance@michigan.gov.

c. For a period of 180 days from the effective date of this order, Respondent's license is restricted to prohibit Michael Goldman, who was identified as Respondent's chief operating officer at the time of the complaint, from engaging in the following activities on behalf of Respondent:

(1) Attending and/or participating in any sampling events

(2) Entering or altering any data in the statewide monitoring system

(3) Engaging in any financial transactions with customers

d. For a period ending on the expiration date of Respondent's renewed license, unless a different time period is specified below, Respondent shall comply with the following:

(1) Adherence to Established/Approved Procedures: Respondent shall strictly adhere to all of its internal quality control procedures and SOPs as approved by the MRA. Any deviations must be documented and promptly reported to the MRA.

(2) Heavy Metals Testing Revalidation: Within 60 days after the date of issuance of this consent order, Respondent shall revalidate and obtain the MRA's written approval of its heavy metals testing method. As part of this revalidation, Respondent shall submit acceptable SOPs that include, at a minimum, updated accuracy, precision, and allowable error. The previous method no longer is approved and the licensee cannot perform testing using the previous method.

(3) Entry of Results in Statewide Monitoring System:

a) Timely Entry of Results: Respondent shall enter all test results into the statewide monitoring system within 72 hours after a COA is generated.

b) Pesticide Test Results: Respondent shall enter into the statewide monitoring system actual test results within the reportable range for all pesticide tests, whether the results are uploaded electronically via a comma-separated values (CSV) file or other method.

(4) COAs: Respondent shall email copies of all COAs that it issues to MRA-Compliance@michigan.gov within 48 hours after the corresponding results are entered in the statewide monitoring system.

(5) Weekly Report and Data Submission: Respondent shall email copies of the following by 8 a.m. every Monday to MRA-Compliance@michigan.gov.

a) A sample repeat log documenting every instance of repeat testing during the preceding week, which includes, at a minimum, the sample number, original result, reason for repeat testing, whether the sample was manipulated in any way, and repeat test result selected for entry into the statewide monitoring system

b) All raw data uploaded to the statewide monitoring system during the preceding week

c) All internal laboratory prep sheets created during the preceding week

d) Any CAPA forms created during the preceding week

e) Maintenance logs for all laboratory instruments for the preceding week
- This requirement ends 180 days from the effective date of this order.

(6) Testing Timeline: Respondent shall complete testing on each sample within 14 days after the sample is received.

(7) Procedure Revision Approval: If Respondent revises any procedures or documents that otherwise require MRA approval for accreditation or other purposes, such revisions also must be approved in writing by the MRA.

5. Respondent must pay a fine in the amount of one hundred thousand and 00/100 dollars ($100,000.00). This fine shall be paid within 90 days of the effective date of this order by check or money order made payable to the State of Michigan with complaint number "19-2-23 *et seq.*" clearly displayed on the check or money order. Respondent shall mail the fine to Department of Licensing and Regulatory Affairs, Marijuana Regulatory Agency, P.O. Box. 30205, Lansing, Michigan 48909, or Respondent may pay online through the Accela Citizen Access Portal (https://aca3.accela.com/MIMM).

6. If Respondent fails to timely pay the fine, Respondent's license shall be suspended until payment is received.

7. Unless otherwise specified in this order, Respondent shall direct any communications to the MRA that are required by the terms of this order to MRA-Compliance@michigan.gov.

8. Respondent shall be responsible for all costs and expenses incurred in complying with the terms and conditions of this consent order.

9. Respondent shall be responsible for the timely compliance with all terms of this consent order, including the timely filing of any documentation. Respondent's failure to comply within the time limitations provided will constitute a violation of this order. The MRA may, in its discretion, grant a written extension of any timeline set forth in this consent order on a case-by-case basis and in response to a written request from Respondent.

10. If Respondent violates any term or condition set forth in this order, Respondent will be subject to fines and/or other sanctions under section 407(1) of the MMFLA, MCL 333.27407(1), and Mich Admin Code, R 333.219.

This consent order is intended to encompass and resolve the specific conduct and violations alleged in the August 16, 2019 formal complaint; the specific conduct and violations alleged in investigation numbers 19-2-33, 19-2-35, 19-2-36, 19-2-41, and 19-2-55; and any additional occurrences of the same conduct and violations that pre-date the formal complaint.

This order shall be effective on the date signed by the MRA's executive director or his designee, as set forth below.

MARIJUANA REGULATORY AGENCY

Signed on: 10/9/2019

By: _____
Andrew Brisbo, Executive Director
Marijuana Regulatory Agency

STIPULATION

The parties stipulate to the following:

1. Respondent does not contest the allegations of fact and law in the complaint. By pleading no contest, Respondent does not admit the truth of the allegations but agrees that the MRA's executive director may enter an order treating the allegations as true for purposes of resolving the complaint.

2. Respondent understands and intends that by signing this stipulation, Respondent is waiving the right under the MMFLA, rules promulgated thereunder, and the Administrative Procedures Act of 1969, MCL 24.201 *et seq.*, to require the MRA to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges.

3. The parties considered the following in reaching this agreement:

   a. In a compliance conference conducted on September 9, 2019, and follow-up communications, Respondent's representatives explained that Respondent has taken steps to improve its business practices and prevent recurrences, including better educating its staff and revising its testing and reporting procedures.

b. Respondent was formally removed from the A2LA accreditation program on September 19, 2019, after requesting to forego its assessment plan with the accrediting body. Respondent understands that it no longer is approved by the MRA to use any of the testing methods previously accredited by A2LA.

c. Respondent understands that it may be subject to more frequent inspections moving forward to ensure compliance with the MMFLA and associated rules.

d. Respondent was cooperative and wishes to resolve the allegations without the need for and expense of an administrative hearing.

4. The MRA's enforcement division director or her designee must approve this proposed agreement before it is forwarded to the MRA's executive director or his designee for review and issuance of the above consent order. The parties reserve the right to proceed to an administrative hearing without prejudice to either party, should the MRA's enforcement division director, executive director, or their designees reject the proposed consent order.

By signing this stipulation, the parties confirm that they have read, understand, and agree with the terms of the consent order.

AGREED TO BY:

Kavita Kale
Enforcement Division Director
Marijuana Regulatory Agency
Dated: 10/9/19

Erika N. Marzorati (P78100)
Assistant Attorney General
Attorney for Complainant
Dated: 10-8-19

AGREED TO BY:

Howard Lutz, Authorized Officer
On behalf of Respondent
Iron Laboratories, LLC
Dated: 10-7-19

Seth P. Tompkins (P63249)
Attorney for Respondent
Dated: 10-7-19

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FORMAL COMPLAINT

Attorney General Dana Nessel, through Assistant Attorney General Erika N. Marzorati, on behalf of the Marijuana Regulatory Agency (Complainant), files this formal complaint against Iron Laboratories, LLC (Respondent), alleging upon information and belief as follows:

1. The Marijuana Regulatory Agency (MRA) is authorized under the Medical Marihuana Facilities Licensing Act (MMFLA), MCL 333.27101 *et seq.*, and Executive Reorganization Order No. 2019-2, MCL 333.27001, to investigate alleged violations of the MMFLA and rules promulgated thereunder, take disciplinary action to prevent such violations, and impose fines and other sanctions against applicants and licensees that violate the MMFLA or rules.

2. Section 407(2) of the MMFLA provides for the summary suspension of a license. The section reads, in pertinent part:

> The [MRA] may suspend a license without notice or hearing upon a determination that the safety or health of patrons or employees is

[1] Executive Reorganization Order 2019-2 transferred all authority, power, duties, functions, and responsibilities of the Department of Licensing and Regulatory Affairs (LARA) under the state's marijuana statutes to the Marijuana Regulatory Agency (MRA), a Type I agency created within LARA. MCL 333.27001(1)(a), (d). The MRA exercises its statutory powers, duties, and functions independent of LARA's direction. MCL 16.103.

> jeopardized by continuing a marihuana facility's operation. If the [MRA] suspends a license under this subsection without notice or hearing, a prompt postsuspension hearing must be held to determine if the suspension should remain in effect.

3. Section 402(12) of the MMFLA provides that the expiration of a license does not terminate the MRA's authority to impose sanctions on the licensee.

FACTUAL ALLEGATIONS AND INTENDED ACTION OF THE MRA

4. Respondent holds a state operating license under the MMFLA to operate a safety compliance facility in the state of Michigan. Respondent's license expired on August 9, 2019. Respondent has a pending application for license renewal.

5. Respondent operated a safety compliance facility in Walled Lake, Michigan, at all times relevant to this complaint.

6. Following an investigation, the MRA determined that Respondent violated the MMFLA and/or rules promulgated thereunder as set forth below:

a. Complaint No. CMP-19-000124

i. On or about July 23, 2019, Respondent performed a compliance test on test package #1A4050100000385000000477.

ii. Respondent detected 0.439 ppm of Myclobutanil in the sample. This result is more than twice the state action limit of 0.2 ppm (parts per million).

iii. Myclobutanil is a highly toxic pesticide that is harmful if swallowed or absorbed through the skin and may release toxic fumes if burned. For this reason, it is listed as a banned chemical active ingredient in Michigan.

iv. Respondent reported the test result for Myclobutanil as 0.439 ppm, a failing result, on the certificate of analysis provided to the client that provided the sample.

v. Respondent failed to enter the failing test result for Myclobutanil into METRC, the statewide monitoring system. Instead, Respondent reported in METRC that the sample passed with 0 ppm detected for all pesticides.

vi. Respondent failed to report the failing test result to the MRA when it transmitted the results to the client.

vii. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).

viii. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

ix. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).

b. Complaint No. CMP-19-000128

i. On or about July 12, 2019, Respondent performed two retests each on Platinum Punch flower (test package #1A4050100000900000005804) and Super Glue flower (test package #1A4050100000900000005853) that previously failed testing for total yeast and mold at a level of 21,000 cfu (colony forming units) at a different safety compliance facility.

ii. Respondent detected and reported in METRC passing results of 0 cfu/gram for both retests on both samples. This result is scientifically implausible, based on the technology Respondent used to conduct the tests and the fact the client that supplied the flower performed no remediation and did not alter the samples prior to their transfer to Respondent.

iii. The same samples were sent to a third safety compliance facility for auditing. The third facility's audit test results detected total yeasts and molds at concentrations exceeding zero, with one result exceeding the state action limit.

iv. Based on the above, Respondent failed to use analytical testing methodologies for required safety tests that may be monitored on an ongoing basis by the MRA or a third party, including either the current version of the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia or an alternative testing methodology approved by the MRA and validated by an independent third party that the methodology followed produces scientifically accurate results for each safety test it conducts, in violation of Mich Admin Code, R 333.247(1).

v. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

c. Complaint No. CMP-19-000097

i. On July 19, 2019, as part of an MRA audit, Respondent conducted a reanalysis test of two infused edible product samples (test packages #1A4050100000900000010101 and 10102) that previously were tested at a different safety compliance facility.

ii. Respondent reported in METRC total THC potency (delta-9 tetrahydrocannabinol concentration) results for both samples as "mg/g" (milligrams of THC per gram of product).

iii. Respondent's reported results failed to account for the total weight of the product and the number of servings in the product.

iv. On the certificate of analysis provided to the client that provided the samples, Respondent reported the THC potency result as "fail[ed] for over maximum level of active Delta 9 THC allowed per container."

v. Respondent failed to enter the failing THC potency test result into METRC. Instead, Respondent incorrectly reported in METRC that the sample passed.

vi. Respondent failed to report the failing test result to the MRA when it transmitted the results to the client.

vii. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).

viii. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

ix. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).

d. Complaint No. CMP-19-000130

i. On or about June 29, 2019, Respondent accepted products for testing from a licensed grower under manifest numbers 0000055601 and 0000062555. The manifests included a total of 17 test packages with the following numbers: 1A4050100001D4E000000008, 0009, 0010, 0011, 0012, 0013, 0014, 0025, 0026, 0027, 0028, 0029, 0030, 0031, 0032, 0033, and 0034.

ii. On certificates of analysis provided to the client that provided the samples, Respondent reported that seven of the samples failed for pesticide results above the state action limit.

iii. Respondent entered the results into METRC for all of the samples that passed testing. However, Respondent failed to enter any of the seven failing results in the statewide monitoring system.

iv. Respondent failed to report the failing test results to the MRA when it transmitted the results to the client.

v. Based on the above, Respondent failed to enter the results into the statewide monitoring system and file with the MRA an electronic copy of a test result for a batch that did not pass the required tests when it transmitted those results to the facility that provided the sample, in violation of Mich Admin Code, R 333.247(14).

vi. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

vii. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).

e. Complaint No. CMP-19-2-23

i. During a sampling event on March 15, 2019, Respondent's chief operating officer, M.G., requested that the client facility not select the "research and development" test in METRC and indicated he would notify the client of any failed results to provide the client an opportunity to remediate the products without "lock[ing] the package up" in METRC.

ii. On March 15, 2019, Respondent collected eight packages from a client for product testing. Respondent weighed only one of the packages, but recorded a weight for each of the eight on the chain of custody form.

iii. Three of the samples Respondent collected on March 15, 2019 (test packages #1A4050100000C81000000785, 0792, and 0788) were less than 0.5% of the weight of the batch.

iv. On March 15, 2019, Respondent failed to tag or label marijuana product with tracking identification numbers (sample tags).

v. On April 1, 2019, Respondent collected four samples (test packages #1A4040100000191000000849, 901, 912, and 998) that were less than 0.5% of the weight of the batch.

vi. On or about April 5, 2019, a lab report revealed that Respondent used method FE 62 to test sample package #1A4040100000191000000953. This method is not included in the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia; was not approved by the MRA; and was not validated by a third-party accreditor to ensure scientifically accurate results.

vii. During an on-site inspection on April 5, 2019, Respondent was unable to provide its field kit for inspection and was unable to verify that its field kit's analytical balance (scale) was properly calibrated.

viii. Following the April 5, 2019 inspection, Respondent provided a calibration certificate that had no serial number listed and was unable to be traced.

ix. Following the April 5, 2019 inspection, Respondent provided the MRA with an internal corrective action report that acknowledged Respondent's scales had an expired calibration that does not conform to the ISO/IEC 17025:2005 or 17025: 2017 standards.

x. During an on-site visit on April 15, 2019, MRA staff discovered five packages of marijuana product that had no METRC tracking label affixed to the package and no tracking information.

xi. Based on the above, Respondent possessed marijuana product without a batch number or identification tag or label, in violation of Mich Admin Code, R 333.236(2).

xii. Based on the above, Respondent failed to use analytical testing methodologies for required safety tests that may be monitored on an ongoing basis by the MRA or a third party, including either the current version of the *Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control* monograph published by the American Herbal Pharmacopoeia or an alternative testing methodology approved by the MRA and validated by an independent third party that the methodology followed produces scientifically accurate results for each safety test it conducts, in violation of Mich Admin Code, R 333.247(1).

xiii. Based on the above, Respondent failed to maintain a quality control and quality assurance program that conforms to ISO/IEC 17025:2005 or 17025:2017 standards, in violation of Mich Admin Code, R 333.247(9)(d).

xiv. Based on the above, Respondent failed to comply with and/or falsified records related to Mich Admin Code, R 333.247. Per Mich Admin Code, R 333.247(15), this requires the MRA to take immediate disciplinary action.

xv. Based on the above, Respondent pre-tested samples, in violation of Mich Admin Code, R 333.247(16)(c).

xvi. Based on the above, Respondent failed to collect a sample size not less than 0.5% of the weight of the batch, in violation of Mich Admin Code, R 333.248(2)(b).

xvii. Based on the above, Respondent failed to ensure marijuana products transferred between facilities had tracking identification numbers assigned by the statewide monitoring system affixed, tagged, or labeled and recorded, in violation of Mich Admin Code, R 333.271(1).

7. Based on the above, Respondent lacks integrity, moral character, and responsibility or means to operate or maintain a marijuana facility. MCL 333.27402(3)(a).

8. Based on the above, Respondent has a history of noncompliance with regulatory requirements in this state. MCL 333.27402(3)(g).

9. Based on the above, Respondent fails to meet other standards in rules applicable to its license category. MCL 333.27402(3)(i).

THEREFORE, based on the above, the MRA gives notice of its intent to impose fines and/or other sanctions against Respondent's license, which may include the suspension, revocation, restriction, and/or refusal to renew Respondent's license.

Under MCL 333.27407(4) and Mich Admin Code, R 333.29494(2), any party aggrieved by an action of the MRA suspending, revoking, restricting, or refusing to renew a license, or imposing a fine, shall be given a hearing upon request. A request for a hearing must be submitted to the MRA in writing within 21 days after service of this complaint. Notice served by certified mail is considered complete on the business day following the date of the mailing.

Respondent also has the right to request a compliance conference under Mich Admin Code, R 333.294(1). A compliance conference is an informal meeting at which Respondent has the opportunity to discuss the allegations in this complaint and demonstrate compliance with all lawful requirements for retention of the license under the MMFLA and/or rules. A compliance conference request must be submitted to the MRA in writing.

Hearing and compliance conference requests must be submitted in writing by one of the following methods, with a copy to the undersigned assistant attorney general.

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

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

If Respondent fails to timely respond to this formal complaint, a contested case hearing will be scheduled to resolve this matter.

Questions about this complaint should be directed to the undersigned assistant attorney general at 517-335-7569.

Respectfully Submitted,

DANA NESSEL
Attorney General

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Dated: August 16, 2019

LF: 2019-0262219-A / Iron Laboratories, LLC / Formal Complaint - 2019-08-16