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