# STATE OF MICHIGAN DEPARTMENT OF REGULATORY AFFAIRS<sup>1</sup> MARIJUANA REGULATORY AGENCY

In the Matter of

ABKO Laboratories, LLC ERG No.: 000060 License No.: SC-000008 ENF Nos.: 20-00066, 20-00081, & 20-00094 CMP Nos.: 20-000210, 20-000392, & 20-000396

#### CONSENT ORDER AND STIPULATION

### CONSENT ORDER

On August 26, 2020, the Marijuana Regulatory Agency (MRA) issued a formal complaint against the medical marijuana safety compliance facility license (SC-000008) of ABKO Laboratories, LLC ("Respondent") under the Medical Marihuana Facilities Licensing Act (MMFLA), MCL 333.27101 *et seq.*, and the administrative rules promulgated thereunder. The formal complaint alleged Respondent violated Mich Admin Code, R 333.236(1), R 222.236(2), R 333.247(1)(b), R 333.247(9)(a), R 333.247(9)(c), and R 333.247(9)(d).

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

Accordingly, for these violations, IT IS ORDERED:

 Respondent must pay a fine in the amount of four thousand five hundred and 00/100 dollars (\$4,500.00). This fine shall be paid within 60 days of the effective date of this order by check or money order made payable to the State of Michigan with enforcement number "20-00066, 20-00081 & 20-00094" clearly displayed on the check or money order. Respondent shall mail the fine to Department of Licensing and Regulatory Affairs, Marijuana Regulatory Agency, PO BOX 30205, Lansing, Michigan 48909.

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www.michigan.gov/MRA
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<sup>&</sup>lt;sup>1</sup> 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. MARIJUANA REGULATORY AGENCY

- 2. If Respondent fails to timely pay the fine, Respondent's license shall be suspended until payment is received.
- 3. The paragraphs of the formal complaint alleging violations of Mich Admin Code R, 333.236(1), R 333.236(2), and R. 333.247(9)(a) are DISMISSED.
- 4. Unless otherwise specified in this order, Respondent shall direct any communications to the MRA that are required by the terms of this order to <u>MRA-LegalHearings@michigan.gov</u>.
- 5. Respondent shall be responsible for all costs and expenses incurred in complying with the terms and conditions of this consent order.
- 6. 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 420.806.
- 7. Upon timely payment of the fine by Respondent, the matters set forth in the formal complaint shall be deemed resolved and closed subject to this Consent Order.

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: 2/18/21

By:

Andrew Brisbo DV CN = Andrew Brisbo DV CN = Andrew Brisbo email = brisbo@michigan.gov C = US 0 = Majiuana Regulatov Agency OU = Executive Director Date: 2021.02.18 07:35:48 -0500\*

Andrew Brisbo, Executive Director Marijuana Regulatory Agency

#### **STIPULATION**

The parties stipulate to the following:

- The remaining facts alleged in the formal complaint, following dismissal of counts alleging violations of Mich Admin Code R, 333.236(1), R 333.236(2), and R. 333.247(9)(a), are true and constitute a violation of the administrative rules promulgated under the MMFLA.
- 2. Respondent understands and intends that by signing this stipulation, Respondent is waiving the right under the MMFLA, administrative 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 formal 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. Respondent provided documentation showing that the erroneous test results entered into the statewide monitoring system on March 17, 2020 were uploaded intentionally by a disgruntled employee in an attempt to disparage the Respondent and potentially cause Respondent to lose its state operating license.
  - b. Respondent admits that the erroneous results that were uploaded on two occasions prior to March 17, 2020 were the result of misinterpretation of data by an employee and was not willful or intentional conduct.
  - c. Respondent provided documentation that it has improved its standard operating procedures and quality control systems to better protect against employee misconduct by:
    - i. Locking equipment so that methods can only be changed by certain staff.
    - ii. Cross-training staff so that one employee is not always in charge of a particular test and results.
    - iii. Requiring results to be reviewed and verified prior to their upload into the statewide monitoring system.
    - iv. Calibrations of equipment are now tracked with employee logins.
    - v. Adopting written procedures for changes to equipment (i.e., calibrations, etc.)
  - d. Upon learning of this situation, Respondent voluntarily shut down and worked with the MRA and others to become compliant and fully ISO certified before performing any testing.
  - e. Respondent provided documentation that it brought on new staff that are better trained in quality control to assist and correct previously identified gaps at its facility.
  - f. 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: Julie Kluytman <sup>Dig</sup>tally signed by: Julie Kluytman by: Cn = Julie Kluytman email = klytman@michiga.gov C = AD Date: 2021.02.17 21:01:04 -0500'

Julie Kluytman, Director Enforcement Division Marijuana Regulatory Agency Dated: 2/17/21

AGREED TO BY: Z hen

Amy Brown, Authorized Officer On behalf of Respondent ABKO Laboratories, LLC Dated: February 17, 2021

Kichard S. Barry

Richard S. Baron (P333798) Attorney for Respondent Dated: February 17, 2021

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ENF No. 20-00066, 20-00081, 20-00094 MRA 5044 4

### STATE OF MICHIGAN DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS MARIJUANA REGULATORY AGENCY

In the Matter of

ABKO Laboratories, LLC ERG No.: 000060 License No.: SC-000008 ENF Nos.: 20-00066, 20-00081, & 20-00094 CMP Nos.: 20-000210, 20-000392, & 20-000396

FORMAL COMPLAINT

The Marijuana Regulatory Agency ("Complainant") files this formal complaint against ABKO 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 the administrative 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 administrative rules.

2. 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 license.

3. Section 206(c) of the MMFLA provides that the administrative rules must ensure the health, safety, and security of the public and integrity of the marihuana facility operations.

4. Respondent's conduct as described below is a risk to public health and safety and/or the integrity of marihuana facility operations.

## FACTUAL ALLEGATIONS AND INTENDED ACTION OF THE MRA

5. Respondent holds an active state operating license under the MMFLA to operate a medical marihuana safety compliance facility in the state of Michigan.

6. Respondent operated at 25900 Dequindre Road, Warren, Michigan, 48901 at all times relevant to this complaint.

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

- a. On February 26, 2020, Respondent removed from its inventory and wasted numerous laboratory samples that were not identified as samples in the statewide monitoring system (METRC), in violation of Mich Admin Code R 333.236(1).
- b. On that same date Respondent had samples that did not have a batch number, identification tag, or label affixed in violation of Mich Admin Code R 333.236(2).
- c. Upon discussing questionable test results reported by Respondent, an employee admitted that its qPCR method had been updated significantly without receiving approval from the MRA or having its updated method validated by an independent third party prior to using the method in violation of Mich Admin Code R 333.247(1)(b).
- d. Respondent reported between March 5, 2020 and March 15, 2020 chemical residue failures at higher levels than normal, and for chemicals that had not been found in test results previously.
- e. Upon discussion of these results with Respondent and review of Respondent's internal corrective action documents, Respondent was not maintaining internal standard operating procedures and did not 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)(c) and (d).
- f. On March 13, 2020, the MRA investigated a complaint against Respondent concerning test results which were believed to be erroneous. The test results MARIJUANA REGULATORY AGENCY 2407 NORTH GRAND RIVER • P.O. BOX 30205 • LANSING, MICHIGAN 48909 <u>WWW.michigan.gov/MRA</u> LARA is an equal opportunity employer/program

including failing results for Myclobutanil for various METRC packages including the following sample tags: 1A40501000058AD000000492, 1A40501000058AD000000494, and 1A40501000058AD000000493.

- g. Analysis of these samples by another laboratory yielded passing test results for these samples. Respondent was not maintaining internal standard operating procedures and did not 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)(c) and (d).
- h. Respondent was licensed on April 25, 2019 and was not approved to perform testing until the end of December 2019. Respondent did not become provisionally accredited within 6 months after issuance of the license in violation of Mich Admin Code R 333.247(9)(a).

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 under the MMFLA and/or the administrative 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:

#### By Mail: Department of Licensing & Regulatory Affairs

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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. The MRA reserves the right to review the formal complaint and amend it should this matter proceed to a contested case hearing.

Questions about this complaint should be directed to the Marijuana Regulatory Agency at (517) 284-8599 or <u>MRA-LegalHearings@michigan.gov.</u>

Dated: 8/26/20

 MARIJUANA REGULATORY AGENCY

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 Claire Patterson, Scientific and Legal Section Manager

Claire Patterson, Scientific and Legal Section Manager Enforcement Division In the Matter of

ABKO Laboratories, LLC ERG No.: 000060 License No.: SC-000008 ENF Nos.: 20-00066, 20-00081, & 20-00094 CMP Nos.: 20-000210, 20-000392, & 20-000396

### PROOF OF SERVICE

I hereby certify that on  $\underline{\$2000}$ , I mailed a copy of the Formal Complaint dated  $\underline{\$2000}$  in the above captioned case by certified mail (return receipt requested) to:

ABKO Labs, LLC 3698 Forge Drive Troy, Michigan 48083

Jessica S. Fox Departmental Analyst Marijuana Regulatory Agency

Department of Licensing & Regulatory Affairs

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