BEFORE THE OKLAHOMA STATE DEPARTMENT OF HEALTH
OFFICE OF ADMINSTRATIVE HEARINGS

STATE OF OKLAHOMA *EX REL* THE OKLAHOMA MEDICAL MARIJUANA AUTHORITY OF THE OKLAHOMA STATE DEPARTMENT OF HEALTH, PETITIONER, v. SHIV KRUPA, LLC, RESPONDENT.	Case No.: MM-2022-362

Filed
MAY 20 2022
Office of
Administrative Hearings

EMERGENCY ORDER OF SUSPENSION

This Emergency Order is issued by the State Commissioner of Health ("Commissioner") of the Oklahoma State Department of Health ("OSDH") under the authority to protect public health, safety and/or welfare granted by 75 O.S. § 314, 63 O.S. § 1-106(B), and 63 O.S. § 427.6(L). OSDH finds that an emergency exists and it is imperative emergency action be taken to protect public health, safety and/or welfare. The existence of said emergency and the requirements OSDH deems necessary to meet the emergency are as follows:

FACTS

1. The Oklahoma Medical Marijuana Authority ("OMMA"), acting as a subdivision of OSDH, is the state agency with statutory authority to license and regulate medical marijuana businesses pursuant to 63 O.S. §§ 420 *et seq.* and 63 O.S. §§ 427.1 *et seq.*

2. Pursuant to 75 O.S. § 314, OSDH, by and on behalf of the Commissioner, has the authority, upon finding that public health, safety or welfare imperatively requires emergency action, to order summary suspension of a license pending proceedings for revocation or other action.

3. Moreover, pursuant to 63 O.S. § 427.6(L), OSDH, by and on behalf of the Commissioner, has the authority upon a finding that an emergency exists requiring immediate action to protect public health or welfare to issue an order for immediate action, including, but not limited to, an order to cease and desist.

4. Respondent owns and operates a medical marijuana business located at [redacted] Shiv Krupa, LLC ("Shiv Krupa") is a licensed medical marijuana testing laboratory who does business as Scale Laboratories and holds license LAAA-C8NH-JZ02, issued by OMMA on or around May 7, 2021 (the "License").

5. An inspection of Shiv Krupa was conducted by OMMA on April 12, 13 and 20, 2022 to review records, testing instruments, testing data, and samples. The inspection found testing violations which pose a threat to public health, safety and/or welfare.

6. Based on the OMMA inspection and subsequent review of Respondent's records, Respondent manipulated testing data. Respondent inaccurately reported passing results to commercial licensees after initial testing showed the medical marijuana and medical marijuana product samples exceeded allowable thresholds for microbials. In particular:

a. One hundred and thirty-eight (138) samples exceeded allowable thresholds for yeast and mold, but were reported to commercial licensees as passing.

b. One (1) sample exceeded allowable thresholds for salmonella, but was reported to a commercial licensee as passing.

c. Five (5) samples exceeded allowable thresholds for E. coli, but were reported to commercial licensees as passing.

7. Respondent did not notify or provide copies of Certificates of Analysis to OMMA when the one hundred and thirty-eight (138) failed testing by exceeding allowable thresholds for microbials.

8. Based on the OMMA inspection and subsequent review of Respondent's records, when a subset of samples failed testing by exceeding allowable thresholds for microbials, Respondent performed a single retest and, if that retest passed testing, reported the result as passing without conducting a second retest.

9. Based on the OMMA inspection, Respondent does not use methodology capable of definitively detecting aspergillus, particularly aspergillus terreus. Despite their inability to test, a review of Respondent's records showed Respondent reported passing results for aspergillus to commercial licensees on Certificates of Analysis between June of 2021 and April of 2022.

10. Based on the OMMA inspection and subsequent review of Respondent's records, Respondent detected the presence of aspergillus in initial testing of nine (9) samples of medical marijuana and improperly influenced the testing process by reporting aspergillus was "Not Detected" and providing passing results to commercial licensees

11. Based on the OMMA inspection, Respondent does not use positive controls in microbiological testing. Respondent did not use negative controls in microbiological testing until March of 2022.

12. Based on the OMMA inspection and subsequent review of Respondent's records, Respondent's microbiological testing is routinely performed by an analyst with less than two years of experience working in a laboratory testing environment.

13. During the inspection of Shiv Krupa, Respondent was unable to provide accurate method validations for microbiological testing. Respondent was unable to provide accurate

correction factors used in heavy metal testing to achieve results reported to commercial licensees. Subsequent to the dates of inspection, Respondent has continued to fail to provide accurate method validations and correction factors used to achieve testing results, despite requests from OMMA.

14. Following the OMMA inspection, OMMA notified Respondent that a passing result issued by Respondent, later failed testing for pesticides, myclobutanil and permethrin at two other licensed testing laboratories. Respondent then manipulated calibration data to produce a result detecting these pesticides.

15. Respondent did not maintain adequate data in a manner to allow it to readily produce the specific calibration used when testing for certain pesticide samples.

16. Based on the OMMA inspection and review of Respondent's records, Respondent failed to run laboratory quality control samples every twenty (20) samples in each analytic run.

17. Based on the OMMA inspection and review of Respondent's records, Respondent failed to run laboratory replicate samples and matrix spike samples or matrix spike duplicate samples.

18. Based on the OMMA inspection and review of Respondent's records, Respondent only runs continuing calibration verifications for pentane, one of thirteen residual solvents required to be tested.

19. During the inspection of Shiv Krupa, Respondent was unable to provide testing records showing runs of laboratory quality control samples associated with analytic runs of specific testing samples as requested by OMMA.

20. Based on the OMMA inspection and review of Respondent's records, Respondent routinely deviates from its Standard Operating Procedures for heavy metals, microbials,

mycotoxin, residual solvents, pesticides, terpenes and potency without maintaining records of the deviations or approval of the deviations by a laboratory director.

21. On May 15, 2022, OMMA, a subdivision of OSDH, instituted a recall of affected samples.

22. Any conclusion of law more appropriately considered a fact is incorporated herein.

CONCLUSIONS OF LAW

23. Respondent's improper manipulation of microbiological testing data is in violation of 63 O.S. § 427.17(M) and 310:681-8-2(d).

24. Respondent's failure to notify OMMA and submit Certificates of Analysis within two days when samples of medical marijuana and medical marijuana product failed required testing is in violation of OAC 310:681-8-3(e)(6).

25. Respondent's failure to perform a second retest with a passing result prior to reporting passing results to commercial licensees after medical marijuana and medical marijuana product samples failed required testing by exceeding allowable thresholds is in violation of 310:681-8-1(j)(4).

26. Respondent's use of a method incapable of detecting aspergillus at the required Limit of Detection found in OAC 310 Appendix A is in violation of 310:681-8-2(g)(1).

27. Respondent's improper manipulating of aspergillus testing data is in violation of 63 O.S. § 427.17(M) and 310:681-8-2(d).

28. Respondent's failure to use positive and negative controls in microbiological testing is in violation of OAC 310:681-8-4(b)(3).

29. Respondent's use of an analyst with less than two years of experience in a laboratory testing environment in the performance of microbiological testing is in violation of OAC 310:681-8-2(f)(2).

30. Respondent's failure to produce method validations and correction factors used in testing in response to requests by OMMA is in violation 63 O.S. § 427.17(O), OAC 310:681-8-2(j), OAC 310:681-5-4(h), and OAC 310:681-5-6(b).

31. Respondent's failure to maintain records of which method validations and correction factors were applied to tests is in violation of OAC 310:681-8-2(i)(9)(A) and (B).

32. Respondent's improper manipulation of calibration data in order to achieve a particular pesticide result is in violation of 63 O.S. § 427.17(M) and 310:681-8-2(d).

33. Respondent's failure to maintain records of calibration data associated with pesticide testing is in violation of OAC 310:681-8-2(i)(9)(A) and (B).

34. Respondent's failure to run quality control samples every twenty (20) samples in an analytic run is in violation of OAC 310:681-8-4(b)(4).

35. Respondent's failure to run continuing calibration verification samples for twelve of the required thirteen residual solvents is in violation of OAC 310:681-8-4(b)(4).

36. Respondent's failure to run laboratory replicate samples and matrix spike samples or matrix spike duplicate samples is in violation of OAC 310:681-8-4(b)(4).

37. Respondent's failure to maintain testing records of runs of laboratory quality control samples is in violation of OAC 310:681-8-2(h)(1).

38. Respondent's failure to maintain records of all deviations from Standard Operating Procedures along with approval of a laboratory director is in violation of 310:681-8-2(g)(4).

39. Any fact more appropriately considered a conclusion of law is incorporated herein.

Public health, safety and/or welfare is placed at risk by the above violations.

40. The above violations pose an immediate risk to the public, including, but not limited to the public consumer of medical marijuana or medical marijuana products, and it is therefore imperative emergency action be taken to protect public health, safety and/or welfare.

ORDER

41. IT IS THEREFORE ORDERED BY THE COMMISSIONER OF HEALTH that based on the authority held by the Commissioner and upon a finding that there is a threat to public health, safety and/or welfare posed by Shiv Krupa, LLC, the medical marijuana business license held by Shiv Krupa, LLC, LAAA-C8NH-JZ02, is hereby suspended.

NOTICE OF OPPORTUNITY TO REQUEST HEARING

42. Upon application to the Department, Respondent shall be offered a hearing within 10 days of the issuance of this Order. Such request for hearing shall be directed to:

Marcia Johns
Administrative Hearing Clerk
Oklahoma State Department of Health
123 Robert S. Kerr Ave.
Suite 1804
Oklahoma City, OK 73102-6406
405-426-8240
405-900-7601
oah@health.ok.gov

Respondent should email OMMALegal@health.ok.gov for questions about licensure.

43. If a hearing is requested, it will be scheduled promptly and Respondent will be notified of the time and place of the hearing. The hearing will be conducted in accordance with the Oklahoma Administrative Procedures Act.

44. Unless the Respondent is an individual, the Respondent shall be represented by an attorney at the hearing.[1] Counsel may present evidence and argument to show why this Order should be set aside or modified.

IT IS SO ORDERED THIS 20th day of May, 2022.

Keith Reed (May 20, 2022 15:45 CDT)

KEITH REED RN, MPH, CPH
COMMISSIONER OF HEALTH
OKLAHOMA STATE DEPARTMENT OF HEALTH

[1] Massongill v. McDevitt, 1989 OK CIV APP 2, holding that a corporation cannot represent itself. See also Title 310, Section 2-21-7, Paragraph A of the Oklahoma Administrative Code.

RETURN OF SERVICE

I, _____, an Investigator for the Oklahoma State Department of Health, maintaining authority as a peace officer with statewide jurisdiction to serve all warrants, summonses, subpoenas, administrative citations, and notices per 63 O.S. § 427.4(F)(2), received this Emergency Order, numbered MM-2022-_____ and executed by Oklahoma State Department of Health Interim Commissioner Keith Reed, on this 20th day of May, 2022, at_____o'clock PM.

(1) On the _____ day of May 2022, I personally served the same Order by delivering a copy thereof, duly certified, upon the person by the name of_____ at the following place and address_____ at the listed date and time_____.

BY: _____