

2. Declaring that HHE proved during the Hearing that its application merited a score that would have ranked HHE within the top 5 applicants such that it would have earned a registration to cultivate, manufacture, and dispense medical marijuana in accordance with NYPHL §§ 3364 and 3365;
3. Ordering Respondent(s), the Commissioner Howard A. Zucker, the Department of Health, the Office of Cannabis Management, and/or the successor governing authority, to register HHE as a Registered Organization to cultivate, manufacture, and dispense medical marijuana in accordance with NYPHL §§ 3364 and 3365 and/or the expedited registration process set forth in NYPHL § 3365-a, and/or any successor legislation;
4. In the alternative, ordering the Department of Health to provide HHE with un-redacted copies of all registered organizations' applications and to produce all eleven Department employees responsible for scoring HHE's application and remanding this proceeding to the Department of Health for a new administrative hearing in accordance with NYPHL § 3365 (3)(b), and/or any successor governing legislation;
5. Remitting this matter to the Department of Health (or the successor governing authority) for further proceeding consistent herewith;
6. Awarding HHE its costs and disbursements, including HHE's attorney's fees; and/or
7. Granting such other, further and different relief as this Court may deem to be just, proper and equitable.

PLEASE TAKE FURTHER NOTICE, that pursuant to CPLR 7804(c) and (e), any answer and supporting affidavits, and a certified transcript of the administrative proceedings shall be served on the undersigned attorneys for HHE at least five (5) days before March 19, 2021;

PLEASE TAKE FURTHER NOTICE that you are directed to file with the Clerk of the Court an administrative record, including a certified transcript of the Department of Health administrative proceedings, along with your answer and answering affidavits.

Dated: February 5, 2021
New York, New York

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medical marihuana (“the Application”) in accordance with New York’s Compassionate Care Act (the “CCA”).²

2. As set forth more fully below, HHE’s application should have ranked it among the top five (5) companies to apply and should have earned it a registration to cultivate, manufacture, and dispense medical marihuana. But the Department’s errors, improprieties, and arbitrary, capricious, and irrational decisions perverted HHE’s nonpareil credentials – specifically, its prior experience producing medical marihuana under highly regulated medical regimes and the \$18.6 million in capital it had amassed prior to applying. As a result, the Department awarded registrations to inexperienced, inept and insolvent applicants (instead of HHE)³ and New York State’s medical marihuana industry has languished as compared to other states.

3. The Department’s transgressions included (but were not limited to): (i) the Department’s failure to release its scoring methodology in advance of inviting companies to apply for a registration (as the State’s finance law and procurement guidelines dictate), (ii) the Department’s failure to adhere to its own ostensible weighting criteria, (iii) the Department’s arbitrary and capricious scoring of the applications, (iv) the Department’s inexplicable delay – which lasted approximately 2 ½ years – in convening an administrative hearing through which HHE and other applicants could appeal the Department’s blatant scoring errors (the “Hearing”), (v) the myriad impediments that the hearing officer, William J. Lynch (“Judge Lynch”), concocted to prevent HHE (and other parties) from obtaining basic evidence necessary to prove

² See New York’s Compassionate Care Act, NYPHL §§ 3360-3369-e (2019); see 10 NYCRR § 1004.5 (application for initial registration) and 10 NYCRR § 1004.6 (consideration of registered organization applications); See also NYPHL § 3365-a(3) (expedited registration of Registered Organization).

³ See “New York’s Marijuana Lobbying Dollars Top \$2 Million By Applicants,” *The Journal News*, April 27, 2017 (“A review of lobbying spending revealed that state marijuana licenses went to companies that were among those that spent the most on lobbying.”).

its case, and (vi) Judge Lynch's mendacious report and recommendation that defies the factual record elicited the Hearing and basic common sense.

4. Notwithstanding the Department's irrational decisions – and the evidentiary obstacles Judge Lynch created – HHE managed to prove that it merited a license to operate as an RO, once the Department's scoring errors were corrected.

5. Among other things, HHE established that it possessed \$18.6 million in capital at the time it had submitted its application. By contrast, other companies to which the DOH awarded registrations either had no money (Fiorello Pharmaceuticals), insufficient capital (Citiva Medical), or worse, were on the verge of insolvency (Bloomfield Industries). The Department however, arbitrarily and capriciously treated Fiorello, Citiva Medical and Bloomfield Industries as if they possessed the same "financial standing" as HHE and scored them accordingly.

6. In other words, the Department concluded (inexplicably) that HHE's \$18 million was equivalent to the zero dollars or negative balance sheets submitted by other applicants. Of course, \$18 million does not equal \$0 (and no rational person can treat those numbers as equivalent). Had Judge Lynch simply corrected this single, glaring mistake (and ignored all the additional scoring errors that HHE also identified or could have identified had it been afforded access to the actual evidence), HHE would have scored within the top five applicants and would have earned a license to operate as an RO in the State of New York.

7. But rather than correct this mistake, award HHE the additional points it deserved, and recommend that the DOH issue HHE a registration, Judge Lynch double-downed on the Department's error. He grossly misconstrued (at best) the evidence before him in an effort to ratify Respondents' absurd arithmetic. More specifically, Judge Lynch disregarded (or misrepresented) (i) the plain and unambiguous terms of the Department's own scoring sheets, (ii)

the sworn testimony of the Department's own witnesses, and (iii) the Frequently Asked Questions that the Department published before soliciting applications. In so doing, Judge Lynch issued a final report and recommendation dated July 31, 2019 (the "Report"),⁴ which the DOH's Order adopts verbatim, that flagrantly defies the Hearing's factual record.

8. Accordingly, HHE is now compelled to bring this Article 78 Petition which seeks an order (i) vacating DOH's Order, (ii) declaring that HHE proved it deserved a registration, (iii) remitting this matter to the DOH (or the successor governing authority) to act in accordance with its findings,⁵ and (iv) compelling DOH (or the successor governing authority) to award HHE a registration to cultivate, manufacture, and dispense medical marijuana in accordance with NYPHL §§ 3364 and 3365 and/or the expedited registration process set forth in NYPHL § 3365-a⁶ and/or the operative law that governs New York's medical marijuana program at the time the Court considers this case.

PARTIES

9. Petitioner HHE is, and was, at all times relevant to this action a New York limited liability company, with its principal place of business in the County of Putnam. Mitch Baruchowitz ("Baruchowitz") is HHE's founding member.

10. Respondent Howard A. Zucker, M.D., J.D, is, and was, at all times relevant to this action Commissioner of DOH, having the powers and duties granted to him in his official capacity, and is named in his official capacity.

⁴ A true and correct copy of the Report is attached hereto as Exhibit C.

⁵ At this writing, the Cannabis Regulation and Taxation Act ("the CRTA") incorporated in the Governor's 2021 budget would strip the DOH of authority over New York's medical marijuana program and vest it instead over a newly created Office of Cannabis Management. The CRTA also would supplant the CCA and regulate both medical cannabis and adult-use (that is, "recreational") cannabis.

⁶ This provision grants the Governor statutory authority to expedite the registrations of companies like HHE that satisfy the qualifying criteria.

11. Respondent DOH is, and was at times relevant to this action, a New York State agency that falls within the definition of “Government Entity” set forth in State Finance Law §§ 139-j and 139-k, having the powers and duties granted it by law.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this proceeding pursuant to New York Civil Practice Law and Rules (“CPLR”) § 7803.

13. Venue is properly laid in Albany County pursuant to CPLR § 505(a).

NEW YORK’S MEDICAL MARIHUANA PROGRAM

14. New York’s medical marihuana program originated in July 2014 with the enactment of New York’s Compassionate Care Act⁷ and with the promulgation in April 2015 of complementary regulations, the Medical Marihuana Program Regulations (“MMPR”).⁸ Taken together, these rules inaugurated a highly regulated medical marihuana regime in New York, authorizing marihuana for a limited set of debilitating illnesses and confining the provision of medical marihuana to specially certified personnel (“the MMJ Program”).

15. To implement this regime, the MMJ Program empowered DOH to award five companies,⁹ called Registered Organizations,¹⁰ the right to cultivate the marihuana plant, to

⁷ See NYPHL §§ 3360-3369-e.

⁸ See 10 NYCRR § 1004.

⁹ Although NYPHL § 3365(9) expressly confines the number of registered organizations to five (5), the DOH augmented the number of R.O.s from five (5) to ten (10) in 2017, just months after Valley Agriceuticals, the 8th place applicant, commenced an Article 78 proceeding in November 2016 charging DOH, *inter alia*, with an opaque and dishonest scoring process and with awarding registrations based on political considerations rather than merit. See Verified Petition, Valley Agriceuticals v. DOH, No. 03578-16 (N.Y. Sup. Ct. 2016) (the “Valley Agriceuticals Petition”). The present Verified Petition validates many of these allegations. A true and correct copy of the Valley Agriceuticals Petition is attached hereto as Exhibit D.

¹⁰ The statutory language in the CCA and MMPR chose “registration” as the term of art to describe the authorization to cultivate, to manufacture, and to dispense medical marihuana. The more common term of art is a “license”. This pleading, accordingly, will use the words “registration” and “license” interchangeably.

manufacture medicinal extracts, and to open four dispensaries each, dispersed throughout the State, to sell the drug to eligible patients. *See* NYPHL §§ 3364 and 3365.

16. However, for aspiring ROs, like HHE, the law erected a high barrier to entry. Prior to applying, HHE and other applicants had to (i) pre-pay a \$200,000 registration fee, (ii) secure the right to use five properties in non-contiguous New York counties (or in the alternative to post a \$2 million bond), (iii) consummate a labor peace agreement, (iv) submit detailed architectural, quality assurance, security, product safety, and operation plans, and (v) amass vast sums of cash to enable the applicant to become operational and then to stay solvent should the applicant earn a license.¹¹ *See* 10 NYCRR. §§ 1004.5 and 1004.6.

THE APPLICATION PROCESS

17. On or about April 2015, the Department (i) released its application instructions, which set forth eleven (11) consideration criteria,¹² and (ii) published a list of Frequently Asked Questions and Answers (the “Q&As”) to guide prospective applicants.¹³

18. However, the Department withheld the respective weights and/or priority to be accorded each of the eleven (11) consideration criteria in violation of the State’s Financing Law¹⁴ and the State’s procurement guidelines.¹⁵

¹¹ Kris Krane, *Lack of Cannabis Banking Hurts Average Small Business Owners, While Wealthy Entrepreneurs Flourish*, FORBES (Jun. 13, 2018), <https://www.forbes.com/sites/kriskrane/2018/06/13/marijuana-banking-constraints-disproportionately-harm-small-businesses/?sh=687c355754ed> (“Consider that the costs associated with launching a state-legal vertically integrated cannabis business... are in the neighborhood of \$4 million to \$6 million, at a minimum. Even opening and operating a retail dispensary to cash flow break-even costs in the range of \$1 million to \$2 million... But without access to traditional business loans, entrepreneurs who are not wealthy but want to start a cannabis business in their community are forced to raise money from investors.”).

¹² A true and correct copy of the Application Instruction is attached hereto as Exhibit I.

¹³ *See* N.Y. Dep’t of Health, Application for Registration as a Registered Organization – Questions and Answers https://www.health.ny.gov/regulations/medical_marijuana/application/docs/q_and_a.pdf. The Q&As also appear as part of the evidentiary record because DOH submitted them as DOH Hearing Exhibit 5.

¹⁴ *See* N.Y. State Fin. Law § 163(2)(b) – (2)(c). Neither the CCA nor the MMPR specified a scoring methodology, so the Department *seemingly* devised one *ab initio*.

19. Furthermore, the Department arbitrarily assigned a numerical score to some consideration criteria while grading other criteria on a pass/fail basis (or no basis at all).

20. The Department, however, did not reveal its scoring method, or the disparate weight it ascribed to the eleven consideration criteria, until **after** it announced its results (not beforehand as the state procurement guidelines dictate). *See supra* note 15.

21. By withholding the scoring methodology and weighting criteria, the Department tarnished the legitimacy of the scoring process.

22. At best, it favored applicants that correctly guessed which sections the Department ultimately would prioritize (and that prioritized those sections accordingly). At worst, it enabled the Department to manipulate the scoring methodology to justify retrospectively its award of registrations to applicants that it had selected for reasons unrelated to applicants' merits.¹⁶

DOH'S DELINQUENT SCORING OF APPLICATIONS

23. Between April 27, 2015 (the date the Department opened the application window) and June 5, 2015 (the date it closed), forty-three (43) companies applied.

24. Most of these applications were more than 1,000 pages in length and the winning applications averaged 2,000 pages. *See infra* ¶ 99.

25. Notwithstanding the length of these applications, DOH claims that it spent the next eight (8) weeks reading each application thoroughly – appraising each application's merits,

¹⁵ N.Y. Procurement Guidelines, at p.30 (May 2014) <https://ogs.ny.gov/system/files/documents/2018/08/psnys-procurement-guidelines.pdf>, (“An RFP must present the criteria that will be used for the evaluation of proposals. At a minimum, the agency must disclose in the RFP the relative weights that will be applied to the cost and technical components of the proposals.”).

¹⁶ *See infra* ¶ 35 (discussing the correlation between an applicant's spending on lobbyists and its final score).

applying a complicated set of weighting criteria, and compiling a valid and reliable score in each of eleven scoring categories all in the course of just three to four hours.¹⁷

26. But during the Hearing, the Department’s senior witness, Dr. Anne Walsh, acknowledged that the expedited timeline compromised the evaluation process.

It was really just grabbing and scoring because we were under a tight timeline for doing this just because, again, if you look at the ambitious deadline that we were given and you start tracking back to how everything had to occur, you know, for plants to be in the ground at the last possible time where you could actually reasonably have a chance of having products on the shelves in January that backed things up, so that we didn't have the luxury of, you know, perusing these [applications] in a slow fashion.

See 6/5/18 Tr. at 1045 (emphasis added).

27. This compressed timetable – coupled with the scorers’ lack of experience in medical marijuana (generally)¹⁸ and their ignorance of the specific scoring category assigned to them¹⁹ – plagued the Department’s evaluations with glaring errors and oversights that resulted in the award of registrations to inexperienced, unqualified, and financially ill-equipped companies.

28. On July 31, 2015, DOH published its final scores for all forty-three (43) applicants along with the ostensible weighting criteria the Department employed in scoring the applications.²⁰

¹⁷ *See* Transcript of Unselected Applicants Under Compassionate Care Act Hearing, June 5, 2018 (“6/5/18 Tr.”) at 1086.

¹⁸ *See* Transcript of Unselected Applicants Under Compassionate Care Act Hearing, March 5, 2019 (“3/5/19 Tr.”) at 451:15-452:17 (“Dr Anne Walsh testified “Have I ever harvest -- cultivated, harvested, extracted, or tested medical marijuana at the time of the applications? No.”).

¹⁹ *See* Transcript of Unselected Applicants Under Compassionate Care Act Hearing, March 26, 2018 (“3/26/18 Tr.”) at 675: 21-24, 677: 13-14. p. 675 (Amanda Wilson, the scorer for the Real Property category admits she has no experience in reviewing commercial leases); *See infra* note 46.

²⁰ N.Y. Dep’t of Health, Medical Marijuana Program, “Evaluation Weights for Scored Criteria” https://www.health.ny.gov/regulations/medical_marijuana/application/evaluation_process.htm.

29. DOH, however, did not reveal how each applicant fared in the ten scored categories. DOH simply posted each applicant's final score.

30. Over the next two and half years, HHE and other applicants sought the scoring sheets to understand how they and the other applicants had been scored. The Department, however, defied all FOIL requests for the scoring sheets, inhibiting HHE, and the other losing applicants, from ascertaining how they performed in each scoring category.

31. It was only at the Hearing, held 2 ½ years after the Department had released each applicant's final score, that the Department finally produced the scoring sheets.

32. Upon information and belief, the Department did not divulge the applicants' performance in each scoring category until the Hearing because it manipulated the scores to justify retrospectively the award of registrations to applicants based upon factors other than their merit.

33. Valley Agriceuticals alleged as much in the Article 78 suit it filed against Respondents on November 28, 2016, Index No. 03578/2016 (Albany County).²¹

34. In addition, newspaper articles published in the Lower Hudson Journal News on April 26, 2017, concluded that:

A review of lobbying spending revealed that state marijuana licenses went to companies that were among those that spent the most on lobbying ... Money flowed to lobbyists from 2013 through 2016, and regulators awarded the initial five licenses in July 2015.²²

35. The chart below, drawn from the foregoing article, evinces a correlation between an applicant's lobbying expenditures and its final score.

²¹ See Exhibit D ¶¶ 10, 59, 60.

²² See "New York's Marijuana Lobbying Dollars Top \$2 million By Applicants," *Lower Hudson Journal News* (April 26, 2017); "What Lobbying Firms Got From New York's Medical Marijuana Applicant," LOHUD (April 26, 2017) <https://www.lohud.com/story/news/investigations/2017/04/26/ny-marijuana-lobbying/100642838/>.

APPLICANT	Money Spent on Lobbyists	Rank in Total Dollars Spent On Lobbying	Rank of Applicant's Final Score	Applicant's Final Score	Registered Organization
Palliatech NY, LLC	\$270,000	1 st	10 th	89.31	YES
Etain, LLC	\$252,292	2 nd	4 th	91.00	YES
Vireo NY LLC	\$211,500	3 rd	2 nd	96.46	YES
Columbia Care	\$209,500	4 th	3 rd	95.08	YES
Bloomfield Industries, Inc.	\$170,000	6 th	5 th	90.59	YES
Great Lakes Medicinals	\$136,000	7 th	11 th	86.86	NO
Citiva Medical, LLC	\$105,000	8 th	8 th	89.49	YES
Brightwater Farm	\$77,500	10 th	14 th	85.92	NO
PharmaCann LLC	\$60,000	11 th	1 st	97.12	YES
Alternative Medicine	\$22,500	14 th	12 th	86.18	NO
HHE – Petitioner	\$15,000	15th	13th	86.17	NO

36. Even if the Department conceived its scoring methodology in good-faith, its delinquent review of the applications it received rewarded inexperienced, inept, and insolvent companies and has begotten an unstable medical marihuana market as well as a stunted medical marihuana program.²³

37. The chart below illustrates the instability. It identifies the applicants that finished one (1) through ten (10), enumerates their total score, and describes their current status. The capital deficits of the four companies ranked 5th through 9th (two companies tied for 8th place) largely account for their turnover.²⁴

²³ <https://mjbizdaily.com/new-york-limited-medical-cannabis-program-might-hinder-a-new-adult-use-market/>

²⁴ See *supra* note 20 for a complete list of all forty-three applicants and their final score.

APPLICANT	FINAL SCORE	RANK	CURRENT STATUS
PharmaCann	97.12	1 st	
Vireo	96.46	2 nd	Criminal charges against New York officers for smuggling marijuana oil from Minnesota to bolster supply ²⁵
Columbia Care	95.08	3 rd	
Etain	91.00	4 th	
Bloomfield Ind.	90.59	5 th	Sold to MedMen for ~\$25M dollars ²⁶
NY Canna	90.43	6 th	Sold to Acreage for \$48M dollars ²⁷
Fiorello Pharm	90.23	7 th	Sold to GTI for \$59.6M dollars ²⁸
Valley Agriceutical	89.49	T-8 th	Acquired by Cresco for ~\$106M ²⁹
Citiva Medical	89.49	T-8 th	Sold to iAnthus for \$18M dollars ³⁰
Palliatech/CuraLeaf	89.31	10 th	

38. Among the companies forced to sell their operations, Bloomfield ranks as the most notorious instance because it collapsed approximately 1 ½ years after DOH had registered it (and determined that it had the equivalent financial standing to HHE).

39. But in many ways, Bloomfield also exemplifies the woeful derelictions in DOH's entire evaluation process. Bloomfield was a company with (i) a twenty-six-year-old CEO, (ii) a

²⁵<https://www.pressconnects.com/story/news/local/2017/02/06/vireo-officials-accused-smuggling-medical-marijuana-ny/97562824/>

²⁶ See *infra* note 35.

²⁷https://www.syracuse.com/news/2018/11/politically_connected_syracuse_group_flips_ny_marijuana_license_for_pot_of_gold.html.

²⁸<https://mjbizdaily.com/green-thumb-completes-60-million-marijuana-firm-acquisition/>.

²⁹<https://mjbizdaily.com/cresco-receives-regulatory-approval-for-new-york-marijuana-license-deal/>.

³⁰ <https://www.recordonline.com/news/20170814/orange-county-medical-pot-company-to-be-sold-for-18m>.

negative balance sheet, (iii) alleged ties to organized crime, and (iv) no operational experience whatsoever.³¹

40. Notwithstanding these obvious deficiencies, Bloomfield somehow managed to place fifth.³²

41. About the only distinction Bloomfield could boast was the \$170,000 it spent in lobbying to Park Strategies,³³ a firm founded by former New York Senator Alfonse D’Amato.

42. Within eighteen (18) months of receiving its registration, Bloomfield fell insolvent³⁴ and in January 2017, had to sell its registration to MedMen Enterprises (“MedMen”). The price was \$25.7 million in cash.³⁵

43. Of course, MedMen has not fared much better than Bloomfield. Once the darling of marihuana investors, MedMen since has hemorrhaged ninety-five percent of its original market value and has precipitated a raft of lawsuits charging its former executives with running the company like a “personal slush fund.”³⁶

44. Similarly, Acreage and iAnthus, the companies that acquired NY Canna and Citiva respectively, are suffering financial woes of their own.³⁷

³¹ In addition, the CEO borrowed the \$400,000 on the company’s balance sheet from his mother. <https://www.politico.com/states/new-york/albany/story/2017/01/medmen-to-acquire-bloomfield-industries-in-medical-marijuana-shakeup-108593>.

³² See *supra* ¶ 35.

³³ See <https://www.lohud.com/story/news/investigations/2017/04/26/ny-marijuana-lobbying/100642838> (“A review of lobbying spending revealed that state marijuana licenses went to companies that were among those that spent the most on lobbying.”); See also [Exhibit D](#) ¶ 56.; See also <https://www.lohud.com/story/news/investigations/2017/04/26/tracking-ny-medical-marijuanaapplicants/100753358/>.

³⁴ See *supra* ¶ 37.

³⁵ See <https://sec.report/otc/financial-report/196027>, p.4.

³⁶ <https://www.forbes.com/sites/chrisroberts/2020/06/19/medmens-failure-is-everything-wrong-with-legal-cannabis-and-is-only-the-first-company-to-implode/?sh=2d8cfb97113c>

³⁷ See bit.ly/3sXTr3R.

45. In fact, much of the dysfunction that currently bedevils New York’s medical marihuana program, in fact, stems from the Department’s award of registrations to companies like Bloomfield that lacked the operational competence and the financial resources necessary to (i) build a capital-intensive cultivation facility, (ii) run a processing plant, and (iii) sustain four retail locations spread across the State,³⁸ rather than to companies like HHE, which boasted both operational competence and prolific financing. *See infra* ¶ 47.

HUDSON HEALTH’S APPLICATION

46. On June 5, 2015, HHE submitted an exemplary application totaling 2,048 pages, documenting the Company’s prodigious financial assets and seasoned expertise in manufacturing medical marihuana (the “Application”).

47. Among other notable credentials, HHE (i) had amassed \$10 million in cash (and \$8.6 million more held in escrow), (ii) boasted prior operational experience in two states (Connecticut and Minnesota) with highly regulated medical marihuana regimes,³⁹ (iii) had spent approximately \$1 million to purchase compliant real estate and/or to execute binding leases for property spanning the state from Erie to Suffolk counties, (iv) had forged an unprecedented partnership with a major research hospital, Montefiore Medical Center, that would have yielded scientific data on medical marihuana’s efficacy for debilitating illnesses, (v) had developed a full formulary of medicinal marihuana products that the Company already manufactured in

³⁸ See “Money Woes Hamper New York’s Medical Marijuana Program,” Democrat & Chronicle, (October 5, 2017); see also “What to Know About Politics, Money, and New Medical Cannabis Legislation, Lower Hudson Journal (May 28, 2019)(“The Health Department previously rejected merger requests submitted regarding Valley Agriceuticals [the 8th highest-scoring applicant] ... and Fiorello Pharmaceuticals [the 7th highest-scoring applicant] ... [because] the two companies had insufficient tangible operational assets to sell to the prospective buyers except their registrations.”).

³⁹ At the time HHE applied, it counted as one of only two companies with previous experience in producing pharmaceutical-grade medical marihuana. By then, HHE’s founding member, Mitch Baruchowitz, was also the founder of Leafline Labs LLC in Minnesota and Theraplant LLC in Connecticut.

Connecticut and Minnesota, (vi) had collected (and submitted) actual lab data that certified its products' consistency, potency, and purity and by doing so, had validated its testing protocols, and (vii) had written precise and methodical SOPs that could enable a layperson to manufacture pharmaceutical-grade marihuana from seed to sale.

48. Despite these exceptional assets, HHE finished thirteen (13th) with a score of 86.17.⁴⁰

49. During the Consolidated Hearing, DOH produced HHE's scoring sheet for the first time. HHE's scoring sheet was marked as DOH Exhibit 14-a.

50. Exhibit 14-a evidenced HHE's performance in ten scoring categories, along with the ostensible conversion factor, and appears below. *See infra* ¶ 53. (A true and correct copy of Hudson Health's Scoring Sheet is attached hereto as Exhibit G.)

51. The scoring sheet reveals myriad anomalies, but among its most manifest is that its conversion factor for product manufacturing and security directly contradict the weighting criteria that DOH published on July 31, 2015 (excerpted below) and that it purports to have applied in awarding HHE's final score.

52. The chart on DOH's website, titled "Evaluation Weights for Scored Criteria," suggests that the Department applied a conversion factor of **0.43** and **0.06** to each applicant's raw scores for "Product Manufacturing" and "Security" respectively.⁴¹

⁴⁰ *See supra* note 24.

⁴¹ *See supra* note 20.

Sub Categories	Applicant Raw Score:	Conversion Factor	Applicant Weighted Score	Percentage of Total Available Points
Miscellaneous	12.00	0.33	4.00	3.2
Product Manufacturing	104.00	0.43	45.00	36
Security	93.00	0.06	6.00	4.8
Transportation & Distribution	21.00	0.19	4.00	3.2
Sales & Dispensing	45.00	0.16	7.00	5.6
Quality Assurance & Staffing	111.00	0.17	19.00	15.2
Real Property and Equipment	18.00	0.56	10.00	8
Geographic Distribution	4.00	3.00	12.00	9.6
Architectural Design	265.05	0.02	6.00	4.8
Financial Standing	3.00	4.00	12.00	9.6
Total Points	676.05		125.00	100

53. However, on the scoring sheet that DOH produced at the Hearing's outset, DOH indicated that it applied a Conversion Factor of **0.40** to "Product Manufacturing" and a Conversion Factor of **0.07** to "Security".

Sub Categories	Applicant Total Points:	Point Factor	Computation of Applicant Final Score	Computation of Applicant Final Score With WEBSITE POINT FACTOR
Miscellaneous	7.50	0.33	2.50	
Product Manufacturing	69.50	0.40	27.92	29.89 (.43)
Security	63.00	0.07	4.34	3.78 (0.06)
Transportation & Distribution	15.50	0.19	2.95	
Sales & Dispensing	27.50	0.16	4.28	
Quality Assurance & Staffing	93.00	0.17	15.92	
Real Property and Equipment	12.00	0.56	6.67	
Geographic Distribution	4.00	3.00	12.00	
Architectural Design Avg.	68.34	0.02	1.59	
Financial Standing	2.00	4.00	8.00	
Organizational Structure	Pass/Pass			
TOTAL POINTS	362.34		86.17	87.58

54. Had DOH used the weighting criteria on the Department's website for Product Manufacturing (.43 * 69.50 = 29.89) and for Security (63 * .06 = 3.78), it would have increased HHE's score from **86.17** to **87.58** and elevated HHE to no lower than 11th place.⁴²

55. But there were many more errors in DOH's scoring of HHE's application that, when corrected, would elevate HHE to no lower than 4th in total weighted score.

56. Two of these errors – one of commission, one of omission – surpass the rest. First, DOH minimized the significance of HHE's copious financial resources by allotting it the identical score in the financial standing category as thirty-eight (38) of the forty-three (43) applicants, including all of the companies awarded licenses.⁴³

57. To do so, DOH equated HHE's \$18.6 million in capital (including \$10 million in cash on hand) with applicants like (i) Fiorello (which finished 7th) that were insolvent under GAAP, (ii) Citiva that had \$240,000 in its bank account, or (iii) Bloomfield Industries (5th), which submitted a balance sheet containing a negative balance because it had accrued \$400,000 of debt.

58. Second, DOH did not credit HHE for its prior experience in successfully producing medical marihuana in Connecticut and Minnesota because the Department dismissed prior experience altogether as a relevant criteria. The colloquy excerpted below dramatizes the absurdity of that DOH's rationale.

Q [David Feuerstein]: Were you aware coming into today, that [] Hudson Health was one of the few applicants that was actually producing cannabis in limited license states?

A [Anne Walsh]: I was aware of that.

⁴² See DOH's Final Scores and Ranking, *supra* note 24.

⁴³ On a scale of '0' to '3', 'Three' signified 'excellent'; 'Two' signified 'average'; 'One' signified 'fair'; and 'Zero' signified 'poor'. See *infra* ¶ 96.

Q: Did that factor into your determination, in any way, when reviewing the application?

A: No...Not in and of itself. If they used that experience, through showing their S.O.Ps and their validation.

Q: Is it fair to say that if you weren't producing cannabis in another state, that you'd have no evidence of validation.

A. Correct.

See 3/5/19 Tr. at 423-425.

59. The exclusion of an applicant's demonstrated competence in manufacturing medical marijuana contravened the "criteria for consideration" in the Application Instructions.⁴⁴

60. More troubling still, this elision resulted in the award of registrations to companies ill-equipped to fulfill their legal mandate.

61. Once again, Bloomfield is emblematic of DOH's failure. Eighteen months after receiving a registration, Bloomfield (i) had opened only two of its four dispensaries (and for only three days a week at that), (ii) could not produce three of the four strains the law required, and (iii) was losing \$500,000 per month.⁴⁵

62. By January 2017, Bloomfield had sold its entire operations to MedMen for \$25 million.⁴⁶

63. Since January 2017, five more of the original ten ROs have had to sell their licenses due to, upon information and belief, inadequate capital and dubious competence. *See supra* ¶ 37.

⁴⁴ *See* Exhibit I at p.4, no. 9 under the "Criteria For Consideration" reads "the moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization." (Emphasis added).

⁴⁵ *See* <https://www.politico.com/states/new-york/albany/story/2016/09/medical-marijuana-company-facing-financial-constraints-seeking-ownership-change-105617>.

⁴⁶ *See* <https://www.politico.com/states/new-york/albany/story/2017/01/medmen-to-acquire-bloomfield-industries-in-medical-marijuana-shakeup-108593>.

64. While large multistate operators now dominate the New York medical market,⁴⁷ many of them still struggle to supply New York's patients with sufficient medicine.

THE ADMINISTRATIVE HEARING

65. On July 31, 2015, DOH published the final scores for all forty-three (43) applicants.⁴⁸

66. Following DOH's publication of the final scores, HHE, along with fourteen (14) other unsuccessful applicants, invoked their right to an administrative review in accordance with NYPHL § 3365(3)(b).

67. DOH, however, did not schedule the Hearing for two and a half years.

68. In the interim, DOH declined persistent requests to schedule a hearing. Moreover, it defied or ignored FOIL requests seeking (i) the rationale for its scoring methodology, and (ii) the scoring sheets documenting each applicant's performance in the ten categories comprising the final score.⁴⁹

69. Whatever the reason for the delay, HHE did not receive a Notice of Hearing⁵⁰ until October 2017. The delay of two and a half years necessarily prejudiced HHE by dimming witnesses' memories, eliminating others' availability, spoliating critical evidence, and curtailing the scope of available remedies.⁵¹

⁴⁷ <https://mjbizdaily.com/new-york-limited-medical-cannabis-program-might-hinder-a-new-adult-use-market/>.

⁴⁸ See *supra* note 24.

⁴⁹ See Exhibit D ¶¶ 10-11, 59-67.

⁵⁰ A true and correct copy of the Notice of Hearing, dated October 11, 2017 is attached hereto as Exhibit E. DOH ostensibly noticed the hearing pursuant to NYPHL § 3393, 10 NYCRR § 51, Article 3 of the State Administrative Procedure Act ("SAPA").

⁵¹ In addition, it exhausted the statute of limitations for an action in the Court of Claims charging the Department with violating Petitioners' constitutional rights and seeking monetary damages. See GML § 50-e(1)(a) (McKinney 1986).

70. The first phase of the Hearing was a consolidated affair in which seven unsuccessful applicants participated (the “Consolidated Hearing”).⁵²

71. The Consolidated Hearing commenced on January 10, 2018, and proceeded over six discrete dates, concluding on June 6, 2018.

72. During the Consolidated Hearing, Judge Lynch only allowed DOH to present its case, restricting petitioners to cross-examining those witnesses that DOH elected to call.

73. DOH, however, only called three of the fourteen (or more) scorers responsible for grading petitioners’ applications – Dr. Nicole Quackenbush (“Dr. Quackenbush”), Amanda Wilson, and Dr. Anne Walsh.

74. At the same time, DOH defied the subpoenas ad testificandum for the remaining eleven scorers.

75. Judge Lynch, as a consequence, confined petitioners to cross-examining only three DOH witnesses – chosen by DOH – and precluded petitioners from calling rebuttal witnesses.

76. On September 11, 2018, Judge Lynch preemptively severed the petitioners’ claims.⁵³

77. As Judge Lynch reasoned: “scheduling further joint hearing dates for the seven Petitioners may cause inconvenience and prejudice.” *Id.*

78. But Judge Lynch never specified who would be “inconvenience[d] and prejudice[d]” by the status quo.

⁵² Of the fifteen unsuccessful applicants identified on the Notice of Hearing, only eight ultimately participated in the Consolidated Hearing.

⁵³ A true and correct copy of Judge Lynch’s Sua Sponte Severance Order is attached hereto as Exhibit F.

79. Upon information and belief, Judge Lynch severed the petitioners' cases to inhibit the petitioners from collaborating further because their cooperation during the consolidated hearing exposed scoring errors, methodological deficiencies, and DOH's use of personnel bereft of the competence or training to evaluate the materials presented them.⁵⁴ By severing the hearing, Judge Lynch prevented petitioners from profiting from the additional scoring anomalies their co-litigants would expose during their case-in-chief and then from marshaling those defects to elevate their final scores.

80. HHE's severed hearing unfolded over three hearing dates – November 20, 2018, January 10, 2019, and March 5, 2019. HHE's founder, Mitch Baruchowitz ("Baruchowitz"), testified on November 20, 2018 and January 10, 2019. On March 5, 2019, DOH re-called Dr. Anne Walsh ("Dr. Walsh") as a rebuttal witness to rehabilitate its case.

81. During the Severed Hearing, Hudson Health demonstrated – and DOH did not refute – that scoring oversights, methodological flaws, and sheer ignorance about the material that DOH scorers had reviewed resulted in HHE not receiving at least nine (9) weighted score points.

⁵⁴ As HHE elicited at the Hearing:

Q. So what's your experience [Amanda Wilson] reviewing commercial property leases and option agreements or rental agreements?

A: [Amanda Wilson]: I don't have any.

Q. Did anyone give you any training on how to review commercial leases?

A: [Amanda Wilson] No.

See 3/26/18 Tr. at 675: 21-24, 677:13-15.

82. In fact, the only witness DOH called to rebut Baruchowitz’s testimony, Dr. Walsh, did not even grade the subsections about which DOH called her to testify.⁵⁵

83. In addition, Dr. Walsh admitted that she had no experience in manufacturing medical marihuana.⁵⁶ Yet Judge Lynch, in the face of HHE’s vociferous objection, let her testify anyway.⁵⁷

84. In the course of Baruchowitz’s testimony, he demonstrated that HHE merited more than nine (9) additional weighted points across the following five application categories: (i) **4.0** more points in Financial Standing (*infra* ¶¶ 149-155);⁵⁸ (ii) **1.1** more points in Real Property;⁵⁹ (iii) **3.0** more points in Manufacturing;⁶⁰ (iv) **0.56** more points in Sales and Dispensing; and (v) **0.66** more points in the public interest component of the Miscellaneous section.⁶¹

85. Credited properly, these 9.32 additional points would have given HHE a score of **95.49** and would have ranked HHE’s Application no lower than third among the forty-three (43) applicants in total weighted score and earned HHE a registration. *See supra* ¶ 37.

⁵⁵ Diane Christiansen and Michael Medved scored Financial Standing. Amanda Wilson scored Real Property. Nicole Quackenbush and Deborah Hotaling scored Sales and Dispensing. And Ken Aldous (“Aldous”) and David C. Spink (“Spink”) scored the cultivation, harvesting, and extraction subsections of the Manufacturing Category. *See also* 3/5/19 Tr. at 420: 20-22.

⁵⁶ *See id.* at 451-452. (“Have I ever harvest -- cultivated, harvested, extracted, or tested medical marijuana at the time of the applications? No.”).

⁵⁷ *See id.* at 385-388, 400-401.

⁵⁸ *See* Transcript of Unselected Applicants Under Compassionate Care Act Hearing, November 30, 2018 (“11/30/18 Tr.”) at 124.

⁵⁹ *See id.* at 102-107. Judge Lynch, in fact, conceded that HHE deserved .56 more points in the Real Property category. *See Exhibit C* at pp.15, 20.

⁶⁰ *See* 11/30/18 Tr. at 242-243.

⁶¹ *See* Transcript of Unselected Applicants Under Compassionate Care Act Hearing, January 10, 2019 (“1/10/19 Tr.”) at 158-160.

86. Notwithstanding the overwhelming weight of the evidence that HHE adduced, Judge Lynch upheld the Department's decision to not register HHE. In so doing, he either (i) disregarded HHE's evidence, or (ii) intentionally distorted it to vitiate its weight and its significance and to camouflage the Department's errors.

87. This Verified Petition anatomizes the intellectual dishonesty of Judge Lynch's reasoning and the Report's conclusion in greater detail below. *See infra* ¶¶ 129-181.

JUDGE LYNCH'S ARBITRARY, CAPRICIOUS, AND PREJUDICIAL RULINGS

88. In retrospect, Judge Lynch's inclination to certify DOH's scoring decisions manifested in a series of arbitrary and capricious evidentiary decisions before the Hearing even began. Upon information and belief, these decisions aimed to foreclose HHE from fully and fairly contesting DOH's scoring decisions and to inhibit HHE from making its case.

89. Among other things, Judge Lynch:

- Declined to enforce HHE's subpoena for un-redacted copies of existing Registered Organizations' applications. In so doing, Judge Lynch prevented HHE from comparing its application to the applications of existing ROs and thereby from proving that its submission was superior and deserving of a registration;⁶²
- Declined to enforce HHE's subpoena for the DOH personnel responsible for grading HHE's Application. In so doing, Judge Lynch prevented HHE from cross-examining them and from directly challenging their scores;
- Peremptorily elevated HHE's burden of proof, making it that much more difficult for HHE to prove its case;
- Effectively enabled the Department to present its case twice.

The Mercurial Standard of Review

90. In the Department's original Notice of Hearing, dated October 11, 2017, its General Counsel characterized Petitioner's evidentiary burden as follows:

⁶² Ample legal precedent supports the proposition that where two licensing applications are mutually exclusive, an effective and fair hearing necessitates a comparative review.

The Petitioner [had to demonstrate] (1) it met[] the requirements for a registered organization set forth in PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 and (2) Petitioner is one of the five most qualified organizations that submitted applications on or before June 5, 2015 for registration as a registered organization.

See Exhibit E.

91. Two months later, Judge Lynch, *sua sponte*, raised this evidentiary burden to an almost insuperable height.

92. Specifically, in a letter dated December 29, 2017, Judge Lynch held,

[T]he scope of the hearing will be limited to whether the Department’s scoring methodology for the applicants for registration as registered organizations to manufacture and dispense medical marijuana under New York’s Compassionate Care Act was consistent with PHL §§ 3360-3369-e and 10 NYCRR Part 1004, and whether the scoring methodology was properly applied.⁶³ (Emphasis added.)

93. This new standard of review entirely eliminated its predecessor’s threshold for success – namely, proof that HHE merited a score among the top five applicants – and conveniently vested Judge Lynch with the unlimited discretion to determine a scoring error’s significance at his whim.

94. This unlimited discretion inheres in Judge Lynch’s use of the word “properly”. Propriety, after all, does not abide in a vacuum. No petitioner could prove — and no arbiter could assess — the “propriety” of the scoring methodology’s use in isolation. “Propriety” is relative. It requires a comparison of multiple applications and an assessment of whether the grader applied the same evaluative criteria consistently in scoring each application.

⁶³ A true and correct copy of Judge Lynch’s Letter, dated December 29, 2017, is attached hereto as Exhibit H.

95. DOH’s own scoring key, excerpted below, illustrates the problem. It consists of a continuum of subjective and relative measures that require the DOH scorer to rate an applicant from ‘excellent’ at one end of the spectrum (three points) to ‘poor’ at the other end (zero points).

96. As set forth below, “Excellent” means “better than average”, and “Average” means an “adequate level of performance”. “Better” and “adequate” are relative terms; they only carry meaning through comparison.

Points	Rating	Rating Description
3	Excellent	The applicant met or exceeded the minimum criteria for the item being evaluated by clearly demonstrating a better than average level of performance.
2	Average	The applicant met the minimum criteria expected for the item being evaluated. The applicant clearly demonstrated an adequate level of performance.
1	Fair	The applicant met the minimum criteria expected for the item being evaluated. However, based on the information provided, the applicant failed to clearly demonstrate an adequate level of performance
0	Poor	The applicant did not meet the minimum criteria for the item being evaluated. The applicant was not responsive to the item being evaluated.

The Un-Redacted Applications

97. To hamper HHE further still, Judge Lynch declined to enforce HHE’s subpoena for the un-redacted copies of all the existing ROs applications. By doing so, he prevented HHE from extrapolating the benchmark that informed “the minimum criteria” or “average level of performance” or “better than average level” or any of the other subjective tropes by which DOH measured an applicant’s performance.

98. This consigned HHE to a speculative exercise using heavily redacted versions of its competitors' submissions.

99. The Department's own website illustrates the added burden this imposed. There, the applications of all forty-three (43) companies that pursued a registration appear for public scrutiny.⁶⁴ However, the typical application redacts approximately 70% of its pages. To cite just the top four scoring applicants alone:

- PharmaCann: 5,078 total pages; 4,283 redacted (84% redacted);
- Vireo: 5,383 total pages; 3,682 redacted (68% redacted);
- Columbia Care: 1,598 total pages; 1177 redacted (74% redacted); and
- Etain: 1,375 total pages, 793 redacted (58% redacted)

100. A typical scoring sheet allots a score to many of the methods, protocols, and procedures contained in these redacted pages (including, but not limited to): (i) a company's cultivation plan, (ii) its extraction methods, (iii) its product certification protocols, (iv) its storage and disposal procedures, (v) its means for producing consistent medical marijuana products, and (vi) the detail of its dispensing labels.

101. But the heavily redacted applications available to HHE during the Hearing (identical versions of which appear on the DOH website) concealed this material.

102. This necessarily prevented HHE from comparing its procedures and protocols in multiple scoring categories against rival applicants and from demonstrating why it deserved a higher score and/or why its actual score was improper.

103. Judge Lynch's rationale for declining to enforce petitioners' request for a subpoena of the un-redacted applications – namely, that the applications contained confidential

⁶⁴ https://www.health.ny.gov/regulations/medical_marijuana/application/applications.htm.

and proprietary information – is entirely spurious⁶⁵ for at least three reasons. A true and correct copy of Judge Lynch’s Letter from August 28th, 2018 rejecting Petitioners subpoena requests is attached hereto as Exhibit J.

104. First, an “Attorneys’ Eyes Only” designation and/or a protective order could have permitted discovery of the un-redacted applications and enabled their introduction at trial without imperiling their proprietary or confidential material.

105. Second, Judge Lynch already closed HHE’s Severed Hearing during Mr. Baruchowitz’s testimony to safeguard HHE’s trade secrets. He easily could have expanded the duration or scope of the closed proceedings to protect other companies’ proprietary material as well.

106. Third, Judge Lynch’s contention that NYPHL § 3371 prohibits disclosure of the ROs’ un-redacted application distorts the provision’s plain meaning. NYPHL § 3371(3) expressly contemplates the disclosure of confidential material in a legal proceeding.⁶⁶ The provision merely requires the presiding officer, like Judge Lynch, to take appropriate measures to secure its confidentiality. Moreover, the provision, antedating the CCA by thirty-two years, aims to protect patient information and to fortify the doctor-patient privilege. It does not apply to the CCA or to application of companies pursuing a medical marijuana registration.

107. Put simply, Judge Lynch’s refusal to compel DOH to produce the un-redacted copies of the existing ROs’ applications was arbitrary and capricious, an error of law, and/or violated lawful procedure.

108. Above all, Judge Lynch denied HHE a fair and thorough hearing and by extension, a full and fair opportunity to demonstrate that it merited a registration.

⁶⁵ 10 NYCRR § 51.9, in pertinent part, authorizes a DOH hearing officer “to issue subpoenas requiring... the production of books, records, contracts, papers and other evidence.”

Department Personnel Defied Subpoenas and Did Not Testify

109. HHE's final score compiled HHE's weighted point totals in ten separate scoring categories. *See supra* ¶ 53.

110. Discrete DOH personnel evaluated and scored each category. But as set forth above, the Department only made three of these individuals available during the Hearing – Dr. Quackenbush (sales and dispensing), Amanda Wilson (real property), and Dr. Anne Walsh (various subcategories in manufacturing).

111. At least eleven other Department employees graded HHE's Application. They are Diane Christiansen and Michael Medved (financial standing), Justin Huber and George Stahidis (real property and geographical distribution), Ken Aldous and David Spink (various subcategories in manufacturing), Debra Hotaling (sales and dispensing), James Gottfrey (architecture), James Miller (architecture), Denise Platt (architecture), and Stephen Sumner (miscellaneous, among other sections).

112. In advance of the Severed Hearing, HHE served all eleven of the scorers named in paragraph 111 above with subpoenas ad testificandum (the "Subpoenas").⁶⁷

113. The Department simply ignored the Subpoenas, and Judge Lynch declined to exercise his authority to enforce the Subpoenas,⁶⁸ concluding as follows:

[Any] testimony by these additional Department employees and former employees would be cumulative on the relevant issue because the criteria, weights, scoresheets and conversion factors are already in evidence, and Petitioner can establish any failure by these potential witnesses to follow the Department's methodology without their testimony.

See Exhibit J at p.5.

⁶⁷ True and correct copies of the subpoenas ad testificandum HHE served on the Department are attached hereto as Exhibit K.

⁶⁸ Judge Lynch's authority to enforce the Subpoenas resides in 10 NYCRR § 51.9.

114. Judge Lynch’s conclusion is specious, illogical, and belied by the record. Indeed, documentary evidence is no substitute for witness testimony, especially where, as here, an applicant’s score in each category and subcategory hinges on the scorer’s subjective determination of the documents themselves.

115. Judge Lynch’s decision is particularly dishonest because he already had curtailed the available documentary record, declining to enforce HHE’s subpoenas for the un-redacted copies of competitors’ applications. *See supra* ¶¶ 97-108.

116. As documented above, there were four tiers in the Department’s scoring scale – ‘Excellent’, ‘Good’, ‘Fair’, and ‘Poor’. *See supra* ¶ 96.

117. Each of these tiers depends upon a subjective benchmark – “minimum criteria” – and demands a relative value judgment: namely, whether the applicant met, exceeded, or fell below this standard.

118. The scoring sheets do not reveal the grader’s rationale for determining whether the applicant met the category’s “minimum criteria” or the ostensible reason why the applicant satisfied or surpassed it (whatever the case may be).

119. This opacity, coupled with the scoring definition’s innate subjectivity, lent to each score an arbitrary and capricious element and immunized its “propriety” from challenge during the Hearing or otherwise (due in no small part to Judge Lynch’s arbitrary and capricious evidentiary rulings).

120. For example, if a scorer decided on no other grounds than his subjective preference that coco coir is a superior growing medium to soil and graded all applicants’

cultivation plans according to this prejudice, HHE would lack the means to ascertain it, let alone to contest it. The scoring sheet simply reads as follows and assigns a corresponding score.⁶⁹

Addresses in adequate detail all methods for
cultivation (seeds and propagation material, soil and fertilization, irrigation, lighting, humidity/moisture, temperature, ventilation, diseases and pests control, use of plant growth regulators, etc.)

121. A valid appraisal of the propriety of HHE’s scores depended upon a cross-examination of the scorer responsible for each section.

122. This is especially true here because Judge Lynch refused to compel DOH to produce its rivals’ un-redacted applications. In so doing, Judge Lynch foreclosed the only other means available to HHE to contest the consistency that lies as the heart of a score’s validity. *See supra* ¶¶ 97-108.

123. In fact, the Consolidated Hearing’s proceedings and Judge Lynch’s Report dramatize the relevance and necessity of both the scorers’ testimony and the un-redacted versions of companies’ applications.

124. During the Consolidated Hearing, a petitioner’s counsel presented Amanda Wilson, the scorer responsible for grading applicants’ “real property,” with letters of intent that Bloomfield submitted (but did not redact) – letters of intent that indicated that Bloomfield had not secured any property at all, as the MMPR required.⁷⁰

125. Upon her cross-examination, Ms. Wilson admitted that (i) she had no experience in reviewing commercial leases, and (ii) she had erred in scoring the real property section by

⁶⁹ See Exhibit G at pp.10-11.

⁷⁰ See 3/26/18 Tr. at 723-724.

awarding more points to Bloomfield than to other applicants that possessed **executed leases** (not letters of intent).⁷¹

126. In light of Ms. Wilson’s testimony, Judge Lynch conceded that HHE deserved **0.56** more points than it had initially received.⁷²

127. Upon information and belief, HHE would have established that even more errors in DOH’s scoring occurred had Judge Lynch required DOH to produce the unredacted applications and permitted HHE to cross-examine the witnesses that scored its application.

128. Judge Lynch’s refusal to enforce the Subpoenas was arbitrary and capricious, an error of law, violated lawful procedure, and above all, it denied HHE a fair and thorough hearing. (Even still, HHE proved that it deserved a total weighted score that would have ranked it among the top 5 applicants. *See infra* ¶¶ 129-180.)

JUDGE LYNCH’S REPORT DEFIES THE EVIDENCE

129. If Judge Lynch presided over a sham hearing, it pales in comparison to the intellectual dishonesty of his Report. Indeed, his Report does not simply lack substantial evidence for its recommendation – that is, sustaining DOH’s decision not to issue HHE a registration – it flagrantly defies the evidence.

130. In fact, despite the myriad procedural obstacles Judge Lynch placed in HHE’s way, HHE managed to extract enough information from a few imperfectly redacted applications to prove that DOH improperly scored the financial standing section of its Application.

131. HHE established that its \$18.6 million in available capital merited one more raw point in financial standing (that is, a ‘3’ [signifying ‘excellent’] instead of a ‘2’ [signifying

⁷¹ *See supra* note 70, at 675:21-24, 677:13-15.

⁷² *See Exhibit C* at pp. 15, 20.

average]],⁷³ which in turn would have resulted in HHE receiving four more weighted points overall.⁷⁴

132. The addition of these four weighted points would have given HHE no less than a **90.73** total weighted score,⁷⁵ placing it no lower than fifth (5th) among all applicants and earning it a registration in accordance with the Department’s original standard of review.

133. To obviate this unrefuted (and irrefutable) conclusion and to skirt its implications, Judge Lynch turned the factual record on its head.

134. First, Judge Lynch misrepresented the plain meaning of the financial standing scoring sheet and elided its *sine qua non* – an appraisal of an applicant’s financial resources. Second, he disregarded the testimony of DOH’s own witness that directly contradicts his interpretation of the scoring sheet. Finally, he fabricated a meaning for “financial standing” that is at odds with the spirit, if not the letter, of the Medical Marihuana Program Regulations (“MMPR”) and DOH’s own Q&As.

135. In fact, there is no evidence – and certainly not “substantial evidence” – that supports the Report’s two central conclusions: that (i) the ‘2’ points that DOH allotted HHE in the financial standing section was rational, and (ii) the Department was justified in not registering HHE as one of the initial Registered Organizations. See Exhibit C at pp.14-15, 20.

⁷³ See *supra* ¶ 96 for the scoring key and the distinction between a score of ‘2’ and a score of ‘3’.

⁷⁴ The Conversion Factor for the Financial Standing Section was 4.0. See *supra* ¶¶ 52-53.

⁷⁵ In 2015, HHE finished 13th with a score of **86.17**. The Report added **0.56** to this total, raising HHE’s score to 86.73. (See Exhibit C at p.20) Adding four more weighted points from Financial Standing (86.17 + 0.56 + 4.0) would bring HHE’s score to **90.73**. This total does not even include the additional **1.1** weighted points HHE would earn if the scoring sheet applied the conversion factors on DOH’s own website. See *supra* ¶ 52. That additional 1.1 point would raise HHE’s score to **91.83** and would rank HHE no lower than 4th.

136. To the contrary substantial evidence elicited at the Hearing supports the conclusion that HHE merited a registration.

New York Medical Marihuana Companies Require Millions of Dollars to Operate

137. The CCA and MMPR promulgated a vertically integrated regime for the sale and distribution of medical marihuana that compelled its licensees to build an indoor cultivation facility, to purchase and to operate expensive extraction machinery, to manufacture medicine in accordance with rigorous safety protocols, and to support four dispensaries widely dispersed throughout the state.

138. This regime necessarily compelled licensees to amass millions of dollars to launch and to operate their businesses. But because the federal government still prohibits marihuana, ROs (like all cannabis companies) cannot borrow money from banks or from traditional lenders.

139. As a consequence, success in raising private capital has become a keystone of the eventual success of medical marihuana companies across the nation.⁷⁶

140. The Department seemingly understood this fact. To wit, DOH made the applicants' financial standing a critical component of its evaluation criteria.

141. According to the weighting criteria the Department released on its website, an applicant's Financial Standing comprised 9.6% of its final score.⁷⁷ (Two and half year later, on HHE's scoring sheet, financial standing comprised 6.4% of HHE's final score. See Exhibit G at p.2).

⁷⁶See *supra* note 11.

⁷⁷See *supra* ¶ 52.

142. Given its critical importance, DOH should have scrutinized each medical marijuana applicant's financial credentials accordingly – appraising the balance sheet and financial statement that the CCA required.⁷⁸ But for some inexplicable reason, DOH did not.

143. DOH's failing is obvious in retrospect: indeed, Bloomfield folded almost one year after it received a registration and four more registered organizations were, upon information and belief, forced to sell their businesses to multi-state operators because they lacked the capital necessary to operate them successfully. *See supra* ¶¶ 38-42.

144. For example, Bloomfield (the 5th place scorer) submitted financial statements revealing a negative cash balance of \$400,000 (meaning it owed \$400,000). Fiorello (the 7th place scorer) was insolvent. And Citiva (the 8th place scorer) possessed only \$400,000 in cash (which was plainly insufficient to open (much less operate) a vertically-integrated cannabis business).

145. By contrast, HHE's balance sheet illustrated that it had \$10,000,000 in cash and an additional \$8,600,000 held in escrow (to be released upon award of a registration). *See supra* ¶ 47.

146. The Department, however awarded the identical score of '2' in the financial standing category to Bloomfield, Fiorello, Citiva and HHE. In fact, DOH awarded thirty-eight (38) of the forty-three (43) companies that applied a '2'.

147. In so doing, the Department necessarily concluded that an entity with negative \$400,000 had the same "Financial Standing" as an entity with \$18.6 million.

148. Such a conclusion epitomizes the kind of arbitrary and capricious administrative decision that warrants judicial intervention.

⁷⁸ *See* 10 NYCRR §§ 1004.5(16).

HHE Proved It Merited Four More Weighted Points For Its Prolific Financial Standing

149. There is no dispute that HHE’s balance sheet recorded \$10,000,000 in cash and an additional \$8,600,000 held in escrow (to be released upon award of a registration). Judge Lynch, in his Report, even acknowledged as much. *See Exhibit C* at p. 14.

150. To HHE’s knowledge, no other applicant came close to this figure.⁷⁹ However, DOH only gave HHE a ‘2’ – meaning it “met the minimum criteria” – instead of the ‘3’ it merited for “exceed[ing] the minimum criteria”. *See supra* ¶ 96 (scoring key).

151. HHE’s entitlement to ‘3’ raw points for financial standing is obvious when juxtaposed with the financial standing of three eventual Registered Organizations – *i.e.*, Bloomfield, Fiorello, and Citiva. The chart below illustrates the disparity.⁸⁰

Registered Organization	Cash on Hand	Raw Score in Financial Standing	Weighted Score in Financial Standing	Final Rank of Applicant	Page, Trial Transcript (11/30/18)
Hudson Health	\$10,000,000	2	8	13 th	p.121
Citiva	\$240,000	2	8	t-8th	p.131
Fiorello Pharmaceuticals	\$0 ⁸¹	2	8	7 th	p.133-5
Bloomfield	(\$400,000)	2	8	5 th	p.142-143
Far(m)ed	\$12,954	2	8	24 th	p.133
Empire State Compassionate Center	(\$226,000)	2	8	28 th	p.136-7

152. If applicants with \$0 (*e.g.*, Fiorello) or a negative balance sheet (*e.g.*, Bloomfield) set the standard for “the minimum criteria expected [and] an adequate level of performance,”

⁷⁹ Had Judge Lynch issued the Subpoenas for the un-redacted applications of the ten existing registered organizations, HHE could have demonstrated as much.

⁸⁰ *See* 11/30/18 Tr. at 121-122, 129-137.

⁸¹ The auditor’s use of “going concern” language on Fiorello’s balance sheet bespoke the company’s insolvency.

then by any objective measure, HHE's \$18.6 million (\$10 million in cash + \$8.6 million in escrow) vastly exceeded this performance criteria and merited a '3'.

153. No credible logic or rational explanation could justify treating \$10 million and \$0 (or negative \$300,000 for that matter) as equivalents.

154. Tellingly, DOH did not attempt to rebut HHE's evidence at the Hearing or the obvious conclusion it compels.

155. In addition, DOH (i) failed to present a single witness to account for its scoring methodology in the financial standing category, and (ii) thwarted HHE's attempt to call as witnesses the two scorers responsible for grading this section, Diane Christiansen and Michael Medved. (In fact, as set forth above, DOH ignored the Subpoenas and then opposed HHE's effort to compel their enforcement.)⁸²

Judge Lynch's Ratification of HHE's Financial Standing Score Defies the Record

156. As set forth above, the unrefuted evidence compels the conclusion that the Department erred in not awarding HHE one more raw point in financial standing, four more weighted points,⁸³ and ultimately, a registration.

157. But to escape this inexorable conclusion – and the implications of DOH's misfeasance – Judge Lynch misrepresented the financial standing scoring sheet (excerpted below)⁸⁴ and falsified the plain meaning of the scoring criteria.

⁸² See Hudson Health Extracts, LLC v. Department of Health, Howard A Zucker, et al, Index No. 907161-18 (2018).

⁸³ The Conversion Factor for financial standing was 4.0. See *supra* ¶ 53.

⁸⁴ During the Hearing, DOH submitted the financial standing scoring sheet for HHE, along with the other forty-two (42) applicants, as Exhibit 8-m (the Financial Standing scoring sheet). See also Exhibit G at p. 21.

Consideration Criteria	Evaluation Process	Evaluator	Score (Pass/Fail)	
Attachment G	The applicant has attached a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application, pursuant to 10 NYCRR § 1004.5(b)(10).	DOH Audit Services Unit	Pass	
Consideration Criteria	Evaluation Process	Evaluator	Score (Pass/Fail)	
Attachment I	The applicant has attached the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant, in accordance with the requirements of 10 NYCRR § 1004.5(b)(10).	DOH Audit Services Unit	Pass	
Item	Consideration Criteria	Evaluation Process	Evaluator	Score
1	Independent Financial Consultant Review	Independent Financial Consultant will review Attachment I and Attachment G to determine financial standing of the applicant.	DOH Audit Services Unit	2

158. As set forth above, the financial standing scoring sheet had three separate components:

- a. SECTION 1, DOH had to determine whether the applicant attached a financial statement setting forth the elements and details of any business transaction connected with the applicant. For that, the applicant would receive a “pass/fail” grade.
- b. SECTION 2, DOH had to determine whether the applicant attached its most recent financial statement in accordance with GAAP that is certified by an independent certified public accountant. Once again, the applicant would receive a “pass/fail” grade.
- c. SECTION 3, **DOH had to review the financial statements identified above and “determine the financial standing of the applicant”. For that, the applicant would receive a grade of ‘1’ through ‘3’.**

159. Despite the plain words of the scoring sheet – which required DOH to “determine the financial standing of the applicant” – Judge Lynch’s Report held as follows:

HHE alleged that its application should have received more than a raw score of 2 points for the Financial Standing subject area because its balance sheet recorded \$10,000,000 in cash and an additional \$8,600,000 in subscriptions held in escrow while other applicants had scored 2 points when their financial statements showed solvency concerns. **However, the consideration criteria for this subject area was whether the applicant had attached two required financial statements, and the rating system provided in the scoring tool for these criteria was on a pass/fail basis. (Exhibit 8m.) Accordingly, the highest score given any**

applicant for this subject area was a raw score of 2 points when the application contained both financial statement...

Accordingly, HHE has not established that it was entitled to a score of 3 points according to the scoring tool because HHE's application only met the criteria for the item being evaluated. Therefore, HHE has failed to establish that the score of 2 points received for this subject area was irrational. (See Exhibit C at p. 14 (emphasis added).)

160. Judge Lynch's interpretation of the scoring sheet belies its plain meaning and mocks its underlying purpose.

161. The operative "consideration criteria for this subject area" was NOT whether the applicant "had attached two required financial statements".

162. Rather, the crux of the applicant's financial standing score lies in the "Independent Financial Consultant Review" of those financial statements – that is, the consultant's appraisal of an applicant's balance sheet, income statements, resources, and ultimately, its financial capacity to construct and to sustain a vertically integrated medical marijuana business.⁸⁵

163. As documented above, the Financial Standing scoring sheet comprises three discrete categories – each with its own delineated 'Consideration Criteria', 'Evaluation Process', and 'Score'.

164. Only the first two categories, Attachment G and Attachment I, are graded pass/fail because they measure a binary result: whether the applicant submitted a financial statement meeting the specified criteria. Section 3, by contrast, stated the following: "**Independent Financial Consultant Will Review Attachment I and Attachment G to determine the financial standing of the applicant.**" (Emphasis added.)

⁸⁵ See MMPR, Section 1004.5(b)(16)(requiring balance sheet from last year and two years of income statements); see also *supra* ¶ 142.

165. According to Merriam-Webster’s dictionary, “to determine” means to “to find out or come to a decision about by investigation, reasoning or calculation.”⁸⁶

166. The use of the phrase “to determine” on the scoring sheet means that DOH’s scorers had to “investigate, reason or calculate” the financial standing of the applicant.

167. Such an investigation, reasoning or calculation plainly required more than just an acknowledgment that “the application contained both financial statements,” as Judge Lynch concluded.

168. Even DOH’s own witness acknowledged as much. In fact, the testimony of Dr. Quackenbush – the then-director of the New York State Medical Marihuana Program⁸⁷ – flatly contradicts Judge Lynch’s formulation.

169. Indeed, on January 10, 2018, Dr. Quackenbush, testified, in pertinent part, as follows:

Q: [Mark Fleisher]: ⁸⁸ Can you now turn over to page – I mean Exhibit 8M? This is the finance tab... And the consideration criteria is listed on this page as for one item, Attachment I, one is Attachment G, and then there’s – and **then there’s one that says just independent financial consultant review**. Can you explain that?

A: [Dr. Quackenbush] Sure. **The first two items listed at the top are pass/fail items that the two reviewers I named were responsible for reviewing**. And, again, going back to the requirements of the application, they were looking at the financial statement with the elements and details of the business transactions, as well as the Applicant’s most recent financial statement meeting those requirements. **And then below that, there was the scored criteria for the – for their review of the information to determine their financial standing**.

Q: Okay

⁸⁶ See <http://bit.ly/3qVHV7h> (quaternary meaning for ‘determine’).

⁸⁷ See Transcript of Unselected Applicants Under Compassionate Care Act Hearing, January 10, 2018 (“1/10/18 Tr.”) at 56.

⁸⁸ Mark Fleisher was the attorney of record representing the DOH. *Id.* at 3.

A: And, again, **a fail here would** – as with the Internet connectivity requirement and the Appendix A **would affect the public interest score**, but would not toss the Applicant out.

Q [Mark Fleisher]: **And the bottom one, the financial review, that gets its own score for this section, though; correct?**

A: [Dr. Quackenbush]: **Correct**

See 1/10/18 Tr. at 121-122 (emphasis supplied.)

170. By testifying that Section 3 “gets its own score” based upon a review of the information (that is, the financial statements submitted in accordance with Section 1 and Section 2), Dr. Quackenbush admitted that an applicant’s financial standing was separate and distinct from whether the applicant “attached two financial statements.” Rather, the scoring sheet demanded an assessment of the financial statements’ contents.

171. In fact, according to Dr. Quackenbush, the absence of financing statements would not affect an applicant’s financial standing at all – it would impact an applicant’s scoring in another category altogether – the public interest subcategory, a subset of the Miscellaneous category.

172. Not surprisingly, Dr. Quackenbush’s interpretation of the scoring sheet also comports with the Q&As that DOH released in 2015. To wit:

Financials - Question 6

Q: Is there any operational budgetary requirement? For example, as part of financials, does the Department expect to *see* money in the bank for the first two years of operation and does New York expect this from the GAAP (question 90, et al)?

A: The Department expects that the applicant’s financial standing will support the real property, equipment and operational needs (including staffing) the applicant proposes.

See the “Q&As,” DOH Hearing Exhibit 5 at 49.

173. Ultimately, neither Judge Lynch's premise nor his conclusion about HHE's financial standing rests on substantial evidence.

174. Judge Lynch's premise – *i.e.*, that the mere submission of two financial statements could earn an applicant a '2' – contradicts (or is entirely inconsistent with) the plain language of the scoring sheet, Dr. Quackenbush's testimony, and the Department's own Q&As. It also defies plain old common sense. Judge's Lynch formulation would reduce an applicant's qualifications for a medical marijuana registration to whether it could prepare and submit a financial statement, regardless of its contents. In other words, Judge Lynch's interpretation of the financial standing criteria would effectively render meaningless the applicant's financial ability to operate a marijuana cultivation, processing and dispensing business.

175. In addition, Judge's Lynch conclusion – *i.e.*, that HHE failed to establish that it was entitled to a score of 3 points – is equally spurious.

176. If applicants with \$0 (*i.e.*, Fiorello) or a negative balance sheet (*i.e.*, Bloomfield) earned '2's in financial standing – and ultimately received medical marijuana registrations – then by any objective measure, HHE proved that its \$18.6 million merited a '3' because it vastly exceeded the performance criteria.

177. As if all of this were not enough (it is), the history of New York's medical marijuana program illustrates the reason why HHE's financial resources were so valuable and vindicates HHE's entitlement to a '3' in financial standing and ultimately, a registration.

178. Bloomfield's negative balance sheet brought ruin within eighteen (18) months.⁸⁹ Citiva sold to multi-state operator iAnthus only six months after DOH approved its registration (and iAnthus since has had to undergo a Court-approved financial restructuring after defaulting

⁸⁹ See 11/30/18 Tr. at 143-144.

on its debt obligations).⁹⁰ Fiorello struggled to raise money, did not open its second dispensary until 2019,⁹¹ and ultimately had to sell its registration to multi-state operator Green Thumb Industries (“GTI”). *See supra* ¶ 37. And none of the original five (5) ROs commenced operations on time.⁹²

179. The above facts demonstrate that HHE – which had \$18 million in immediately available capital – merited four (4) more points in the financial standing category (*i.e.*, one raw score point multiplied by a conversion factor of four).

180. These four (4) additional points – coupled with the .56 points the Report added to HHE’s score (*See Exhibit C* at p.15) – would have raised HHE’s final score to **90.73** points (at the very least), earning it the 5th highest score and entitling it to a registration.

181. Thus, DOH’s original decision to deny HHE a registration, Judge Lynch’s Report affirming it, and the final Order adopting the Report do not rest on “substantial evidence”.

FIRST CAUSE OF ACTION- CPLR § 7803(4)

182. HHE repeats and re-alleges paragraphs 1 through 181 as if fully set forth herein.

183. The Department held the Hearing over nine dates between January 10, 2018 and March 5, 2019 to adjudicate HHE’s entitlement to a registration to cultivate, process and dispense medical marijuana in accordance with NYPHL §§ 3360-3369.

184. The Hearing proceeded in accordance with the statutory mandate specified in NYPHL § 3365(3)(b). Judge Lynch presided.

185. On July 31, 2019, Judge Lynch issued the Report.

⁹⁰ <https://mjbizdaily.com/new-york-medical-cannabis-company-sells-18-million-cash-stock/>; *See also* <https://mjbizdaily.com/marijuana-firm-ianthus-gets-canadian-court-approval-for-restructuring-plan/>

⁹¹ <https://www.democratandchronicle.com/story/money/business/2019/02/06/rochester-second-medical-marijuana-dispensary-fiorello-university-avenue-pain-relief/2712251002/>

⁹² <https://www.democratandchronicle.com/story/news/2016/01/05/columbia-care-medical-cannabis-rochester-dispensary/78312914/>

186. The Commissioner of the Department of Health adopted the Report as its own and issued a final order on January 10, 2020 (“the Order”).

187. The Order is not supported by substantial evidence. The Order – and derivatively, the Report upon which it rests – was unreasonable and irrational for all the reasons set forth above.

188. Among other reasons, the Report grossly distorts DOH’s own scoring criteria for an applicant’s financial standing.

189. As a result, the Report depreciated the significance of the \$18.6 million in capital HHE possessed and diminished HHE’s financial standing score.

190. Indeed, HHE proved, by a preponderance of the evidence during the Hearing, that it merited one (1) more raw score point in financial standing and four (4) more weighted points in total, bringing its final score to a total no lower than **90.73** points, ranking it no lower than 5th, and entitling it to a registration.

191. By defying the unrefuted weight of evidence HHE adduced at the Hearing, the Order and the Report flouted the factual record and therefore do not rest on substantial evidence.

192. HHE, accordingly, demands a judgment annulling and reversing the Order and the Report and in turn, ordering DOH (or apposite governing authority) to issue HHE a registration to cultivate, to extract, and to dispense medical marihuana in accordance with the CCA and the MMPR.

SECOND CAUSE OF ACTION—CPLR § 7803(4)

193. HHE repeats and re-alleges paragraphs 1 through 192 as if fully set forth herein.

194. The Department held the Hearing over nine dates between January 10, 2018 and March 5, 2019 to adjudicate HHE's entitlement to a registration to cultivate and to dispense medical marihuana in accordance with NYPHL §§ 3360-3369.

195. The Hearing proceeded in accordance with the statutory mandate specified in NYPHL § 3365(3)(b). Judge Lynch presided.

196. On July 31, 2019, Judge Lynch issued the Report.

197. On January 10, 2020, the Commissioner issued the Order.

198. The Order is not supported by substantial evidence. The Order – and derivatively, the Report upon which it rests – was unreasonable and irrational.

199. The conversion factor DOH employed on HHE's scoring sheet to derive its total weighted score deviates from the conversion factor DOH published on its website in 2015.

200. According to the conversion factors on the Department's website, HHE is entitled to 1.41 additional weighted points (*see supra* ¶ 52), bringing its final weighted score to a total no lower than **92.14** and ranking HHE no lower than fourth, and entitling it to registration.

201. As such, the Order and the Report defy the factual record and do not rest on substantial evidence.

202. HHE, accordingly, demands a judgment annulling and reversing the Order and the Report and in turn, ordering DOH (or apposite governing authority) to issue HHE a registration to cultivate, to extract, and to dispense medical marihuana in accordance with the CCA and the MMPR.

THIRD CAUSE OF ACTION—CPLR § 7803(3)

203. HHE repeats and re-alleges Paragraphs 1 through 202 as if fully set forth herein.

204. The Commissioner's Order and Judge Lynch's Report was arbitrary and capricious, violated lawful procedure, and/or was affected by errors of law, as set forth in CPLR § 7803(3), because the hearing officer either refused to issue (or to enforce) the Subpoenas for un-redacted copies of the applications of the existing registered organizations and denied HHE the practical ability to prove its application's superiority by comparison.

205. A fair administrative hearing and meaningful administrative review of the scoring of HHE's Application depended upon a comparative evaluation of HHE's Application with the applications of current registered organizations.

206. The breadth and extent of the redactions in the existing registered organizations' applications denied HHE the ability to prove its Application's superiority and deprived HHE of a full and fair hearing and meaningful administrative review.

207. The Report, and in turn, the Order, are therefore predicated upon arbitrary and capricious rulings, unlawful procedure, and/or affected by errors of law.

208. HHE, accordingly, demands that the Department provide HHE with un-redacted copies of the original applications of all ten (10) current registered organizations and that it remand this matter for a new administrative hearing; or in the alternative, it demands a judgment annulling and reversing the Order and the Report and ordering DOH (or the successor governing authority) to issue HHE a registration to cultivate, extract, and dispense medical marihuana in accordance with the CCA and the MMPR.

FOURTH CAUSE OF ACTION—CPLR § 7803(3)

209. HHE repeats and re-alleges Paragraphs 1 through 208 as if fully set forth herein.

210. The Commissioner's Order and Judge Lynch's Report was arbitrary and capricious, violated lawful procedure, and/or was affected by errors of law, as set forth in CPLR

§ 7803(3), because Judge Lynch refused to issue and then to enforce the Subpoenas that HHE had served on eleven (11) DOH personnel responsible for scoring HHE's Application.

211. A fair administrative hearing and meaningful administrative review of the scoring of HHE's Application depended upon HHE's ability to question DOH's scorers, to ascertain their logic, and to contest their rationale.

212. Judge Lynch's conclusion that the testimony from DOH scorers would be "cumulative, privileged, or irrelevant material" belies the factual record and the cross-examination of one of the few scorers DOH made available.

213. By defying the Subpoenas, DOH and/or Judge Lynch deprived HHE of a full and fair hearing and meaningful administrative review.

214. As such, the Report, and in turn, the Order, are predicated upon arbitrary and capricious rulings, unlawful procedure and/or are affected by errors of law.

215. HHE, accordingly, demands that the Department produce all eleven (11) scorers responsible for grading HHE's Application and that it remand this matter for a new administrative hearing; or in the alternative, it demands a judgment annulling and reversing the Order and the Report and ordering the DOH (or the successor governing authority) to issue HHE a registration to cultivate, to extract, and to dispense medical marijuana in accordance with the CCA and the MMPR.

FIFTH CAUSE OF ACTION—CPLR § 7803(3)

216. HHE repeats and re-alleges paragraphs 1 through 215 as if fully set forth herein.

217. The Order adopting the Report as its own, was arbitrary and capricious, violated lawful procedure, and/or due process of law and/or was affected by errors of law, as set forth in

CPLR § 7803(3), because DOH stalled for two and half years before scheduling an administrative hearing pursuant to NYPHL § 3365(3)(b).

218. This unreasonable delay dimmed witnesses' memories, eliminated witnesses' availability, spoliated critical evidence, curtailed the scope of available remedies, and impugned the integrity of DOH's scoring sheets and HHE's performance according to the weighting criteria.

219. This unreasonable delay deprived HHE of due process of law and/or denied HHE a full and fair hearing.

220. HHE, accordingly, demands a judgment annulling and reversing the Order and the Report and ordering DOH to issue HHE a registration to cultivate, to extract, and to dispense medical marihuana in accordance with the CCA and the MMPR.

SIXTH CAUSE OF ACTION—CPLR § 7803(1), § 7803(2), §7803(3)

221. HHE repeats and re-alleges paragraphs 1 through 220 as if fully set forth herein.

222. The Commissioner Zucker and DOH devised a scoring methodology and weighting criteria for their review of HHE and others' medical marihuana applications, but they did not release this scoring methodology and weighting criteria until after they had published the final scoring results.

223. DOH also altered the scoring categories between the time it released the Application Instructions (April 2015) and the time it announced the final results (July 2015). Then it altered the conversion factor(s): the conversion factor published on its website (July 2015) differ from the conversion factor identified on HHE's scoring sheet (disclosed to HHE in January 2018).

224. New York State Finance Law §§ 163(2)(b)-(2)(c) and New York State Procurement Guidelines required DOH, at a bare minimum, to disclose the relative weights to be used to score an applicant's financing and technical competence and to apply them consistently and uniformly in advance of accepting applications.

225. By withholding its scoring methodology and/or by altering the formula, DOH failed to satisfy this minimum requirement and thereby exceeded its statutory authority or proceeded in excess of its legislative mandate and executive jurisdiction or acted arbitrarily and capriciously.

226. HHE, accordingly, demands a judgment annulling and reversing the Order and the Report and ordering DOH to issue HHE a registration to cultivate, to extract, and to dispense medical marihuana in accordance with the CCA and the MMPR.

WHEREFORE, HHE respectfully requests the Court enter an order and judgment against the Respondent pursuant to CPLR § 7803 and grant HHE the following relief:

(a) Annulling and vacating the Department's Order (the "Order"), dated January 10, 2020, which rejected Petitioner's application as a Registered Organization to dispense and to manufacture medical marihuana in accordance with NYPHL §§ 3364 and 3365, because the Order does not rest upon substantial evidence, and/or is arbitrary and capricious;

(b) Declaring that HHE proved during the Hearing that its credentials merited it a registration to cultivate, manufacture, and dispense medical marihuana in accordance with NYPHL §§ 3364 and 3365;

(c) Ordering Respondent(s), the Commissioner Howard A. Zucker, the Department of Health, the Office of Cannabis Management, and/or the successor administrative agency to register Petitioner as a Registered Organization to cultivate, manufacture, and dispense medical

marihuana in accordance with NYPHL §§ 3364 and 3365 and/or the expedited registration process set forth in NYPHL § 3365-a, and/or successor governing legislation;

(d) In the alternative, (i) ordering the Department of Health to provide Petitioner with un-redacted copies of all registered organizations' applications and to produce all eleven Department employees responsible for scoring Petitioner's application and remanding this proceeding to the Department of Health for a new administrative hearing in accordance with NYPHL § 3365 (3)(b), and/or (ii) remitting this matter to the Department of Health (and/or successor governing agency) for further proceeding consistent herewith;

(e) Awarding Petitioner costs and disbursements, including Petitioner's attorneys' fees; and/or

(f) Granting such other, further and different relief as this Court may deem to be just, proper and equitable.

Dated: February 5, 2021
New York, New York

FEUERSTEIN KULICK LLP

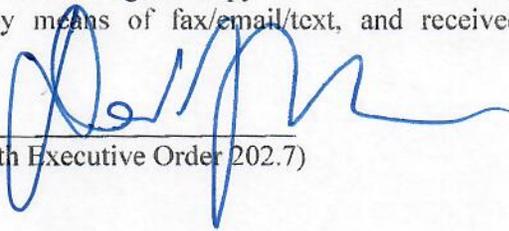
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*Attorneys for Petitioners Hudson
Health Extract, LLC*

ACKNOWLEDGEMENT

On the 5th day of February 2021, before me, the undersigned, a Notary Public in and for said State, personally appeared MITCH BARUCHOWITZ, by way of real time audio and live video conference which allowed for direct interaction between us in accordance with New York State Executive Order No. 202.7, issued March 19, 2020, as extended. MITCH BARUCHOWITZ is personally known to me or proved to me on the basis of satisfactory evidence displayed during the video conference to be the individual whose name is signed in the foregoing Verified Petition. He acknowledged to me that he was at that time physically present in the County of New York, State of New York. A legible copy of the Verified Petition was transmitted directly to the undersigned by means of fax/email/text, and received by the undersigned on the same day it was signed.

Notary Public (in accordance with Executive Order 202.7)



DANIEL J. BROWN
Notary Public, State of New York
Reg. No. 02BR6365915
Qualified in Westchester County
Commission Expires October 16, 2021

EXHIBIT A

STATE OF NEW YORK : DEPARTMENT OF HEALTH
-----X

IN THE MATTER

OF

HUDSON HEALTH EXTRACTS, LLC,

An Unselected Applicant for Registration as a Registered
Organization to Manufacture and Dispense Medical Marijuana
Under New York's Compassionate Care Act,

Petitioner,

ORDER

Pursuant to Article 33 of the Public Health Law of the
State of New York and Part 1004 in Title 10 (Health)
of the Official Compilation of Codes, Rules and
Regulations of the State of New York (NYCRR).

COPY

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Hudson Health Extracts, LLC, requested a hearing to challenge the determination to not register Hudson Health Extracts as a Registered Organization authorized to manufacture and dispense approved medical marijuana products in New York State. The Department served a Notice of Hearing upon fifteen petitioners and a consolidated hearing was held on January 10, February 26, March 26, April 25, June 5 and June 6, 2018. Hudson Health Extract's appeal was severed from the other petitioners and three additional days of hearing were held at the Offices of the New York State Department of Health, 150 Broadway, Menands, New York, before William J. Lynch, Administrative Law Judge.

The Department appeared at the hearing and was represented by Mark Fleischer, Esq., Division of Legal Affairs, Bureau of Administrative Hearings. Hudson Health Extracts appeared at the hearing and was represented by Mitch Baruchowitz, Esq., Managing Partner during the consolidated hearing, and by David Feuerstein, Esq., and Matthew S. Schweber during the final three severed hearing days. Evidence was received, and witnesses were sworn and examined. A transcript of the proceedings was made. On July 31, 2019, the Administrative Law Judge issued

his Report and Recommendation.

NOW, on reading and filing the Notice of Hearing, the record of the hearing and the Administrative Law Judge's Report and Recommendation, I hereby adopt the Report and Recommendation of the Administrative Law Judge as my own; and

IT IS HEREBY ORDERED THAT:

The Department's decision to not grant Hudson Health Extract's Registered Organization application is sustained.

Dated: Albany, New York

January 10, 2020

BY: *Scott D. ...* FOR
Howard A. Zucker, M.D., J.D.
Commissioner of Health

EXHIBIT B

TOLLING AND EXTENSION AGREEMENT

The parties hereto, Hudson Health Extracts, LLC (“HHE”), a New York limited liability company, and the New York State Department of Health (“DOH” or the “Department”) consummate this Tolling and Extension Agreement as of December 15, 2020 (the “Tolling Agreement”).

On January 10, 2020, DOH Commissioner, Howard A. Zucker, adopted the Report and Recommendation of the Department’s Administrative Law Judge and sustained the Department’s decision not to grant HHE’s application for registration as a Registered Organization in accordance with Article 33 of New York’s Public Health Law (the “Commissioner’s Order”). HHE’s time to file an action contesting the Commissioner’s Order pursuant to Article 78 of New York’s Civil Practice Law and Rules began to run accordingly on January 10, 2020.

The purpose of this Tolling Agreement however is (1) to effectuate New York Governor Andrew Cuomo’s Executive Order(s) 202.8 (entered March 7, 2020) and 202.14, 202.28, 202.38, 202.48, 202.55, 202.67 (entered April 7, 2020, May 8, 2020, June 6, 2020, July 7, 2020, August 5, 2020, September 4, 2020, October 5, 2020 respectively) suspending the statute of limitations for “the commencement, filing, or service of any action” until November 3rd, 2020, at the earliest (the “Governor’s Tolling Orders”); (2) to extend the parties’ last Tolling and Extension Agreement (memorializing the Governor’s Tolling Orders), which would expire on January 8, 2021, by another thirty (30) days, notwithstanding the expiration of the Governor’s Tolling Orders; and (3) to memorialize the tolling and extension of the statute of limitations for HHE to commence an Article 78 action challenging the Commissioner’s Order to **February 5, 2021**, an extension to which the parties herein mutually agree.

WHEREAS HHE invoked its right to an administrative hearing, which commenced on January 10, 2018, challenging the Department’s determination not to register HHE as a Registered Organization authorized to cultivate, manufacture, and to dispense medical marijuana products in New York State in accordance with N.Y. P.H.L. §§ 3360-3369-e;

WHEREAS HHE concluded its administrative hearing before administrative law judge William J. Lynch (“Judge Lynch”) on March 5, 2019;

WHEREAS Judge Lynch, in an Administrative Law Judge’s Report and Recommendation, dated July 31, 2019, recommended that “the Department’s decision to not yet grant HHE’s registered organization application be sustained” (“Judge Lynch’s Report”).

WHEREAS Commissioner Howard A. Zucker, MD, JD, rendered a final order on January 10, 2020 adopting Judge Lynch's Report and upholding the Department's decision not "to grant Hudson Health Extract's registered organization application" (the "Commissioner's Order");

WHEREAS New York Practice Law and Rules § 217, in the absence of the Governor's Tolling Order, would require HHE to file an Article 78 Proceeding by May 10, 2020; that is four months from the date, January 10, 2020, that the Commissioner's Order became final and binding;

WHEREAS the Governor's Tolling Order(s) created a blanket toll and halted the statute of limitations' clock for all claims for no less than four months and by agreement of the parties hereto, originally extended the date by which HHE had to file an Article 78 Proceeding until, at least, January 8, 2021;

WHEREAS the parties now mutually agree to toll and to halt the statute of limitations clock beyond the date of the parties last Tolling and Extension Agreement as well as the date that the Governor's Tolling Order(s) expire and to extend the date by which HHE has to file an Article 78 Proceeding challenging the Commissioner's Order until, at least, **February 5, 2021**;

NOW THEREFORE, in consideration of the promises made herein and other good and valuable consideration, the receipt of which is hereby acknowledged, the DOH and HHE, intending to be legally bound, hereby agree as follows:

1. The foregoing Recitals are specifically incorporated herein as part of the Agreement below.

2. To effectuate the Governor's Tolling Order(s) and the parties' mutual agreement to extend it, HHE's time to commence an Article 78 Proceeding contesting the Commissioner's Order—and Judge Lynch's Report which underlies it—shall be tolled and is hereby extended until at least **February 5, 2021**, notwithstanding the expiration of the Governor's Tolling Orders, the statute of limitation, laches, estoppel or otherwise, to the extent they apply (the "Expiration Date").

3. This Agreement does not extend or revive claims where the statute of limitations expired prior to the Governor's Tolling Orders.

4. By written agreement, the parties may extend the Expiration Date to accommodate new Tolling Orders issued by the Governor or alternatively, as they see fit under the circumstances.

5. Each party who executes this Agreement hereby certifies that he or she is duly authorized to do so by his/her respective client, and expresses his/her intention, by executing this Agreement, to be bound by its terms.

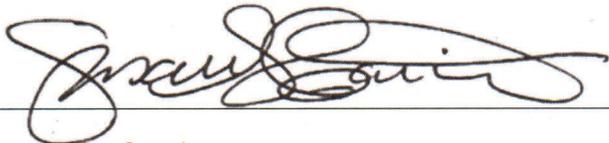
6. This Agreement shall be construed under and governed by the laws of the State of New York.

7. This Agreement contains the entire agreement between the parties relating to the Governor's Tolling Orders and the Expiration Date. Modifications, extensions, or amendments shall be in writing and shall be executed by both parties.

8. This Agreement may be signed in counterparts. Copies, facsimiles, and electronic signatures shall be deemed as good, and as binding, as originals.

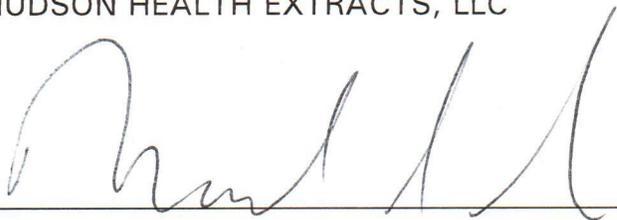
IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first set forth below.

NEW YORK STATE DEPARTMENT OF HEALTH



Susan G. Cartier
Director of Litigation

HUDSON HEALTH EXTRACTS, LLC



FEURESTEIN KULICK LLP, counsel for Hudson Health Extracts, LLC

Matthew S Schweber
David Feuerstein

Dated: New York, New York
December 15, 2020

EXHIBIT C

-----X

IN THE MATTER OF

OF

HUDSON HEALTH EXTRACTS, LLC,

ADMINISTRATIVE
LAW JUDGE'S
REPORT AND
RECOMMENDATION

An Unselected Applicant for Registration as a Registered
Organization to Manufacture and Dispense Medical Marihuana
Under New York's Compassionate Care Act,

Petitioner,

pursuant to Article 33 of the Public Health Law of the
State of New York and Part 1004 in Title 10 (Health)
of the Official Compilation of Codes, Rules and
Regulations of the State of New York (NYCRR).

-----X

TO: The Honorable Howard A. Zucker, M.D., J.D.
Commissioner, New York State Department of Health

The Compassionate Care Act (CCA) was enacted in July 2014 and codified as New York Public Health Law (PHL) §§ 3360-3369-e. Pursuant to PHL § 3365(9), the Department of Health (Department) was directed to register five organizations to manufacture and dispense approved medical marijuana products in New York State (Registered Organizations or ROs) and was granted the discretion to register additional ROs. The Department finalized the regulations implementing the statute in April 15, 2015 and accepted RO applications through June 5, 2015. The Department ranked the 43 applications which were received and initially granted registrations to the five highest ranked applicants in July 2015. Approximately a year later, the Department then granted registrations to the sixth through tenth ranked applicants.

Hudson Health Extracts, LLC. (HHE) was ranked thirteenth and is one of at least fifteen applicants that requested a hearing because they had not yet been granted a registration. The

Department served a Notice of Hearing upon fifteen of these unsuccessful applicants scheduling a consolidated hearing to commence on December 5, 2017. The Notice of Hearing stated the basis for the appeal as follows:

The Department's decisions to not select the Petitioners for registration as one of the initial registered organizations, as authorized pursuant to PHL § 3365(9), are based on the Department's determinations, pursuant to PHL §§ 3365(3) and 10 NYCRR § 1004.6, that five other organizations submitted an application that was superior to that submitted by each of the Petitioners, in that the application better demonstrated the organization's ability to meet the requirements for registered organizations set forth under PHL §§ 3364 and 3365, and 10 NYCRR §§ 1004.5 and 1004.6. (ALJ Ex. 1.)

At the request of the parties, I adjourned the first hearing date and considered questions raised about the scope of the hearing. On December 29, 2017, I issued a ruling that "the scope of the hearing would be limited to whether the Department's scoring methodology for the applicants for registration was consistent with PHL §§ 3360-3369-e and 10 NYCRR Part 1004, and whether the scoring methodology was properly applied." (ALJ Ex. 2.)

The hearing which commenced on January 10, 2018 was held at the Offices of the New York State Department of Health, 150 Broadway, Menands, New York. The Department appeared by Mark Fleischer, Esq., Division of Legal Affairs, Bureau of Administrative Hearings. HHE was one of the seven Petitioners that appeared at the hearing and was represented by Mitch Baruchowitz, managing partner.

The consolidated hearing with the seven Petitioners continued on February 26, March 26, April 25, June 5 and June 6, 2018. The Department presented the testimony of three witnesses and obtained the admission of documents into evidence. All seven Petitioners were given an opportunity to cross-examine the Department's witnesses. Commencing a consolidated record of these hearings had the benefit of some judicial economy in the presentation of the Department's evidence, but difficulties such as maintaining confidentiality of trade secrets and scheduling

hearing dates amenable to all parties became manifest when it came time for the seven individual Petitioners to present their evidence. Due to these obstacles, I severed the seven Petitioners' claims on September 11, 2018, and I scheduled individual hearing dates for each of the Petitioners.

On November 1, 2018, I was advised that HHE had retained two attorneys as counsel for the hearing: Matthew Schweber, Esq., and David Feuerstein, Esq. I denied HHE's November 20, 2018 request that I reconsider rulings which I had made two months earlier. (ALJ Ex. 3, 4.) I note that HHE had appeared at the hearing by its managing partner who is an attorney since the first hearing day on January 10, 2018 and at the time of my prior ruling on August 28, 2018.

The individual hearing of Petitioner HHE was held on November 30, 2018, January 10, 2019 and March 5, 2019. The parties' written submissions were received on May 31, 2019. The record for this hearing consists of the transcripts and exhibits from the six days of the consolidated hearing as well as a transcript for the three hearing days held for HHE individually.

The following documents related to the application evaluation process were offered by the Department and admitted into evidence at the consolidated hearing:

- Ex. 1 – Instructions for the Application for Registration as a RO
- Ex. 2 – DOH-5138 – Form for the Application for Registration as a RO
- Ex. 3 – DOH-5145 – Appendix A Form
- Ex. 4 – DOH-5146 – Appendix B Form
- Ex. 5 – Questions and Answers (Q&A) on Application
- Ex. 6 – Application Evaluation Process Flowchart
- Ex. 7 – Application Review Assignments
- Ex. 8a – RO Evaluation Tool
- Ex. 8b – Evaluation Ratings: Explanation & Definitions
- Ex. 8c – Real Property Evaluation Criteria
- Ex. 8d – Transportation and Distribution Evaluation Criteria
- Ex. 8e – Security Evaluation Criteria
- Ex. 8f – Miscellaneous Evaluation Criteria
- Ex. 8g – Organizational Structure Evaluation Criteria
- Ex. 8h – Manufacturing Evaluation Criteria
- Ex. 8i – Staffing Evaluation Criteria
- Ex. 8j – Sales and Dispensing Evaluation Criteria

- Ex. 8k – Architectural Program Evaluation Criteria
- Ex. 8l – Geographic Distribution of Dispensing Facilities Evaluation Criteria
- Ex. 8m – Financial Evaluation Criteria
- Ex. 9 – Application Pass/Fail Checklist
- Ex. 10 – Applicant Information Checklist
- Ex. 11 – Curriculum Vitae of Nicole Quackenbush, Pharm.D.
- Ex. 12 – Curriculum Vitae of Ann C. Walsh, M.D., Ph.D.
- Ex. 13 – Curriculum Vitae of Amanda Wilson
- Ex. 14a – Scoresheets for the 43 RO Applications
- Ex. 14c – Summary of the 43 RO Application Scores and Ranks
- Ex. 14d – Evaluator Scoresheets for the 43 RO Applications
- Ex. 15 – Summary of Evaluation Process, Criteria, Weights and Results
- Ex. 16 – Steps to Access Applications and Evaluations on Shared Drive
- Ex. 17a – Curriculum Vitae of Kenneth M. Aldous, Ph.D.
- Ex. 17b – Curriculum Vitae of David Charles Spink, Ph.D.
- Ex. 17c – Curriculum Vitae of Bryan C. Duffy, Ph.D.
- Ex. 17d – Curriculum Vitae of Lei Li, Ph.D.
- Ex. 18 – Documents Reviewed by Dr. Walsh prior to Testimony

During the consolidated hearing on April 25, 2018, Petitioner New York Medical Growers (NYMG) offered three items which were received in evidence:

- NYMG Ex. A - Flash Drive containing Redacted RO Applications
- NYMG Ex. E – Unredacted Pages from NYMG’s Appendix B in RO Application
- NYMG Ex. F – Unredacted Pages from NYMG’s Appendix B in RO Application

The Department’s Record Access Office determined that HHE’s RO application contains information that is personal, trade secret, critical infrastructure, or security related information that could endanger a person’s life or safety. Therefore, a redacted version of HHE’s application has been released to the public. When this matter was severed from the consolidated hearing, HHE offered a copy of its unredacted application which was admitted in evidence and is contained on a flash drive marked as HHE Ex. A. During its individual hearing, HHE based its presentation on HHE Ex. A and the record from the consolidated hearing including the redacted applications of the other applicants which was already in evidence as NYMG Ex. A.

FINDINGS OF FACT

The following Findings of Fact were made after a review of the entire record in this matter. Numbers below in parentheses refer to exhibits (denoted by the prefix "Ex.") or transcript page numbers in the consolidated hearing transcript, pages 1 through 1477 ("Consol. T.") or the separately heard HHE hearing transcript pages 1 through 458 ("HHE T."). These citations refer to evidence found persuasive in arriving at a particular finding:

1. On July 7, 2014, the Compassionate Care Act (CCA) was signed into law. The Department set eighteen months after this enactment as the timeframe within which medical marijuana should be made available to patients in New York State. (Consol. T. 60.)

2. The Department established a Medical Marijuana Program (MMP) within the Office of Narcotics Enforcement to carry out the tasks required to effectuate the CCA. (Consol. T. 61.)

3. The Department's regulations for implementing the CCA were formally adopted on April 15, 2015 as Part 1004 in Title 10 of the NYCRR. (Consol. T. 63.)

4. Pursuant to the CCA, a Registered Organization (RO) is authorized to lawfully manufacture and dispense marijuana for certified medical use in New York State. (PHL § 3364.)

5. The Department's MMP developed a RO application process. On April 27, 2015, the Department published notice of its initiation of the process and posted the application and instructions on the MMP webpage. (Consol. T. 64, 66.)

6. Nicole Quackenbush, a Doctor of Pharmacy, has been the Director of the MMP since its inception in August 2014, and she oversaw the development and implementation of the several aspects of the program including the regulations as well as the RO application and selection process. Dr. Quackenbush also participated in reviewing and scoring the Sales and Dispensing subject area of the applications. (Consol. T. 59-60, 68, 75-76, Ex. 7, 11.)

7. Amanda Wilson, an MMP manager, coordinated the RO application scoring process. She has a master's degree in Business Administration with a concentration in Health Systems Administration. She assisted in creating the scoring tool, trained the reviewers, assisted reviewers with any issues that arose, retrieved individual scoresheets from reviewers and compiled the results. Ms. Wilson also participated in reviewing and scoring the Miscellaneous, Real Property & Equipment, and Organizational Structure subject areas of the applications. (Consol. T. 341, 345-349, 352-353, Ex. 7, 13.)

8. Ann Walsh, M.D., Ph.D., is the Associate Director of Medical Affairs for the Department's Wadsworth Laboratory. She is a medical doctor, board certified in internal medicine with a doctorate in the fields of microbiology, immunology and molecular genetics. Dr. Walsh assisted in the development of the application subject areas of Product Manufacturing and Quality Assurance, and she participated in scoring those sections. (Consol. T. 1052, 1079-1085; Ex. 12.)

9. The forms for the RO application and its several required attachments and appendices were developed by the MMP in a period of approximately four months. The goal of the MMP staff was to tie the various elements of the application to the statutory and regulatory requirements imposed on ROs. (Consol. T. 64-65, 181, 346, 1081-1082.)

10. In developing the application, the MMP staff received assistance and guidance from the Department's Bureau of Contracts which utilizes a competitive bid process when the State procures a vendor for goods or services. (Consol. T. 64, 68, 233, 837, 844-845.)

11. The RO application elicited information on ten subject areas related to an applicant's proposed operation: (1) Product Manufacturing, (2) Security, (3) Transportation and Distribution, (4) Sales and Dispensing, (5) Quality Assurance and Staffing, (6) Real Property and Equipment, (7) Geographic Distribution, (8) Architectural Design, (9) Financial Standing, (10) Miscellaneous

Regulatory Requirements. The MMP's goal was for the application to capture the information needed to assess an entity's ability to achieve regulatory compliance as an RO. (Consol. T. 30, 65, 346, 1081; Ex. 1-4.)

12. The MMP created an evaluation tool to score the applications in the form of an Excel document that contained individual score sheets for each subject area (Consol. T. 93-94, 359; Ex. 14a.)

13. The individual score sheets listed the criteria being evaluated within that subject area based on the regulations and usually identified where the applicant had been instructed to provide the required information. (Consol. T. 1155-1156; Ex. 14d.)

14. Most of the subject area score sheets used a rating system that scored the criteria with zero through three points based on the extent to which the reviewer deemed the applicant to have met that criteria. The four classifications were poor, fair, average and excellent. (Consol. T. 207; Ex. 8b.)

15. The subject area score sheets for Product Manufacturing, Quality Assurance & Staffing and Geography had their own rating system. (Ex. 8h, 8i, 8l.)

16. Some subject areas had attachments and criteria that were scored as pass or fail. Failing one of these criteria could result in the applicant receiving a lower score but would not disqualify the applicant from further consideration. However, the applicant, if selected, would be required to meet the criteria before being issued a registration. (Consol. T. 82-83; Ex. 8g, 8j, 8m.)

17. Within some subject areas such as Product Manufacturing, the MMP assigned a weight for the number of points earned which would cause the raw score to be multiplied by that assigned weight. (Ex. 8h.)

18. Dr. Walsh and other reviewers in the Department's Wadsworth Laboratory expressed the opinion that an applicant's raw score in the various subject areas should also be given different weight depending on the importance of that subject area to ensuring patient safety. Accordingly, they suggested that subject areas such as Manufacturing and Quality Assurance should be given greater weight toward an applicant's final score. (Consol. T. 1082-1082, 1401-1402.)

19. To address this concern, the Department designed a conversion factor for each of the subject areas, so the total points earned by an applicant in each subject area would be multiplied by that factor. These subject area weighting formulas were established before the Department received applications and were built into the approved scoring template. The computer program containing the scores applied the conversion factor and added the final scores of the subject areas to create a final overall score and ranking for each applicant. (Consol. T. 366-367, 737; Ex. 14c.)

20. In response to actual questions regarding the application process, the MMP formulated a Q&A which was posted on its website in mid-May 2015. (Consol. T. 210; Ex. 5.)

21. On June 4 and 5, 2015, 43 applicants submitted their application packages to the Department. Each application package contained one hard original application, nine hard copies of the original, and one DVD or flash drive with an electronic copy of the original. (Consol. T. 69; Ex. 15.)

22. The MMP calculated that the selected ROs would need approximately four to six months to grow the marijuana plants and produce products for sale depending on the type of manufacturing. Therefore, the Department's timeframe for reviewing and scoring the applications to select the ROs was limited to approximately eight weeks after the application submission date if the Department was to meet its goal of making medical marijuana available to patients by January 2016. (Consol. T. 200.)

23. A single Department employee reviewed all 43 application packages when they arrived and confirmed that they were all complete insofar as containing the application items needed for evaluation. (Consol. T. 69-70.)

24. The Department assigned employees based on their area of expertise to assist the MMP with reviewing and scoring the various subject areas of the applications. For example, licensed pharmacists were assigned to review the subject area of Sales and Dispensing. Architects from the Department as well as the New York State Dormitory Authority (DASNY) were assigned to review the subject area of Architectural Design. Employees from the Department's Division of Administration reviewed the subject area of Finance. Scientists from the Department's Wadsworth Laboratory reviewed sections involving Product Manufacturing and Quality Assurance & Staffing. (Consol. T. 68, 119-121, 137, 1067, 1075-1079, 1093, 1103-1104; Ex. 12, 17a-17d.)

25. For the subject area of Architectural Design, the 43 applications were split among four architects who were reviewers. For all other subject areas, an assigned reviewer reviewed all 43 applications. (Consol. T. 118-120, 130-131, 215; Ex. 14d.)

26. In order to prevent a single reviewer from having too great an impact on the process, a pair of reviewers independently reviewed most subject areas of every application and their scores were averaged. This type of review was taken with regard to the subject areas of Product Manufacturing, Security, Transportation and Distribution, Sales and Dispensing, Quality Assurance and Staffing, Real Property and Equipment, and Miscellaneous Regulatory Requirements. (Consol. T. 101, 944, 1089; Ex. 14a.)

27. All reviewers assigned scores independently; however, paired reviewers were asked to re-review a scored criterion if one reviewer had given a score of 0 points and the paired reviewer had given a pre-weighted score of 2 or 3. (Consol. T. 116-117, 361-362, 1090-1091.)

28. Ms. Wilson transferred the scores from the reviewers' subject area score sheets to the related section of the score book template for each applicant. (Consol. T. 359-362.)

29. Staff members from the Department's Division of Administration with assistance from MMP employees then ensured that the reviewers' scores had been properly entered in the score book by comparing the entries with the individual score sheets. The Excel program for the score book then computed the scores and ranked the 43 applications. (Consol. T. 367-368, Ex. 14c.)

30. HHE is a New York limited liability company, formed by Mitch Baruchowitz. (T. 20.)

31. HHE received an overall score of 86.17 which caused it to be ranked 13th among the 43 applicants. (Ex. 14c.)

32. Unless another scale was provided, the standard rating used by evaluators was as follows:

Points	Rating	Rating Description
3	Excellent	The applicant met or exceeded the minimum criteria for the item being evaluated by clearly demonstrating a better than average level of performance.
2	Average	The applicant met the minimum criteria expected for the item being evaluated. The applicant clearly demonstrated an adequate level of performance.
1	Fair	The applicant met the minimum criteria expected for the item being evaluated. However, based on the information provided, the applicant failed to clearly demonstrate an adequate level of performance
0	Poor	The applicant did not meet the minimum criteria for the item being evaluated. The applicant was not responsive to the item being evaluated.

(Ex. 8b.)

33. The consideration criteria for scoring the Real Property subject area was the applicant's ability to demonstrate that he or she possesses or has the right to use sufficient property, buildings and equipment to properly carry on the activity described in the operating plan. The scoring methodology indicated that an applicant would score from 0 to 3 points for providing "copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option

contracts showing right to use sufficient land, buildings, other premises, and equipment identified, or proof of \$2,000,000 bond provided.” (Ex. 8c.)

34. Ms. Wilson, who reviewed this subsection of the Real Property subject area, scored an applicant with two points if the applicant provided unexecuted leases and lease proposals which had not been finalized. (HHE T. 676-677, 687-692.)

35. HHE spent approximately \$1,000,000 dollars to acquire real estate, and its application contained a purchase contract for a proposed manufacturing facility, a fully executed lease for three proposed dispensaries and a purchase contract for the fourth proposed dispensary. Yet, HHE also received a score of 2 points for this subsection. (HHE T. 30, 121-122; HHE Ex. A, pages 210-323.)

DISCUSSION

HHE requested this hearing and has the burden of proof pursuant to SAPA § 306(1) and 10 NYCRR § 51.11(d)(6). In order to prevail, HHE must demonstrate that the Department’s decision to not yet grant HHE’s RO application was not supported by substantial evidence.

When the CCA was enacted, any number of entities could have submitted RO applications. PHL 3365(3)(a) states that the Commissioner “shall grant a registration” if satisfied that an applicant meets certain listed criteria and any other conditions as determined by the Commissioner. At first glance, this sentence of the statute suggests that any applicant meeting the established criteria and conditions was entitled to have its application granted; however, PHL 3365(3)(a)(v) states that the Commissioner must be satisfied that it is in the public interest to grant the registration and that the Commissioner may consider whether the number of ROs in an area will be adequate

or excessive to reasonably serve the area. Therefore, the CCA gave the Department discretion in determining the number and the location of the ROs whose applications should be granted.

Another section of the CCA which references the number of RO applicants is PHL 3365(9) which states that the Commissioner “shall register no more than five registered organizations” but then later states in the following sentence that the Commissioner “may register additional registered organizations.” The first of these sentences which limits the Commissioner to registering no more than five ROs appears inconsistent with granting the Commissioner discretion to register additional organizations in the following sentence. The Department implemented this section of the statute by limiting its initial grant of registration to five applicants and then exercising its discretion to grant an additional five applications approximately one year later. Having considered the statute in its entirety, the Department’s actions in this regard was a reasonable manner of resolving this apparent inconsistency.

The Department received 43 RO applications, reviewed the applications, scored the applications, and has now granted registrations to the ten applicants which had received the highest scores. HHE’s application was reviewed and received a score placing it thirteenth among the 43 applicants. Therefore, HHE has not yet been granted a registration. Since the Department was authorized to select among the RO applicants, the issue then becomes whether HHE has established that the Department had no rational basis for either the design or implementation of its selection process.

The Department presented the testimony of three witnesses who explained the application selection process: Nicole K. Quackenbush, Pharm.D., the Director of the MMP; Amanda Wilson, a Health Program Administrator 2 and Manager in the MMP; and Ann C. Walsh, M.D., Ph.D., the Associate Director for Medical Affairs in the Department’s Wadsworth Center. These three

witnesses explained their consideration of the statutory and regulatory requirements in the design of the RO application and how that consideration is reflected in the specific terminology of the application itself.

The testimony of these witnesses and the documents in evidence establish the method the MMP developed to evaluate the RO applications. The MMP created a spreadsheet for each subject area to serve as a scoring tool for the applications. Within each subject area, the MMP defined one or more specific items which were assigned a certain number of points or were designated as pass/fail. Within some of those subject areas such as Product Manufacturing, the MMP assigned a weight for the number of points earned which would cause the raw score to be multiplied by that assigned weight. The MMP also designed a conversion factor for each of the subject areas, so the total points earned by the applicant in each subject would be multiplied by that factor. The MMP designed the computer program to apply the conversion factor and add the final scores of the subject areas which created a final overall score for each of the applicants.

The Department's evidence also established the manner in which the application evaluation method was implemented when the applications were received. The MMP identified Department employees based upon their areas of expertise to review assigned subject areas and record a score on the spreadsheet for that subject area. A single reviewer scored an assigned subject area for all 43 applications, except responsibility for the Architecture Design subject area was divided among four architects. For some areas, two reviewers were assigned to independently review a subject area of the 43 applications, and the applicant received an average of the two scores. The Department's witnesses credibly testified that these measures were taken to both foster consistency and to reduce the risk of a single reviewer having too great an impact on the selection process.

HHE claims that the validity of the final scores suffered because the Department did not disclose the weighting formula applied to the different subject areas until after the applications were evaluated. The testimony of the Department's witnesses, however, established that these factors were set in place before the Department received the completed applications and provided an explanation for applying different weights depending on the importance of the subject area. In particular, the Department determined that an applicant's ability to safely manufacture approved medical marijuana products with a consistent cannabinoid profile was an important concern. Therefore, the department developed a weighting factor that allocated approximately 36 percent of the total available points to the subject area of Product Manufacturing and allocated approximately 15 percent of the total available points to the subject area of Quality Assurance. As such, the Department has established a reasonable basis for incorporating its weighting system into the evaluation process.

The second aspect of this inquiry was whether the Department's methodology was properly applied to HHE's application.

HHE alleged that its application should have received more than a raw score of 2 points for the Financial Standing subject area because its balance sheet recorded \$10,000,000 in cash and an additional \$8,600,000 in subscriptions held in escrow while other applicants had scored 2 points when their financial statements showed solvency concerns. However, the consideration criteria for this subject area was whether the applicant had attached two required financial statements, and the rating system provided in the scoring tool for these criteria was on a pass/fail basis. (Ex. 8m.) Accordingly, the highest score given any applicant for this subject area was a raw score of 2 points when the application contained both financial statements. HHE has not established that the statute or regulations required the Department to rank an applicant higher if the applicant could

demonstrate that it possessed superior financial resources. Accordingly, HHE has not established that it was entitled to a score of 3 points according to the scoring tool because HHE's application only met the criteria for the item being evaluated. Therefore, HHE has failed to establish that the score of 2 points received for this subject area was irrational.

HHE claimed that its application should have scored higher in the subject area of Real Property because it contained fully executed leases for its manufacturing and dispensary sites. The Department conceded that HHE articulated sound bases for crediting those applicants that had entered into binding agreements for manufacturing and dispensary sites but claimed that HHE could not demonstrate that the Department's approach lacked a rational basis. (Department's brief at p. 20.) However, in contrast to the Financial Standing subject area which scored the consideration criteria on a pass/fail basis, the Real Property area required the reviewer to use a score of 0 to 3 points. (Ex. 8b, 8c, 8m.) Although I agree that the Department has articulated a rational basis for granting a score of 2 points for this subsection if an application contained proposed leases, HHE has then established that its application exceeded the minimum criteria by clearly establishing a better than average level of performance because its application contained executed leases and binding purchase contracts. Therefore, HHE would be entitled to a score of 3 points according to the scoring tool created by the MMP. If HHE's score for the subject area of Real Property is increased by one point from a score of 7 to a score of 8, the overall score of its application would be raised from 86.17 to 86.73. (The conversion factor for the Real Property subject area was .56 percent.)

HHE also claimed that its application should have scored 3 points for a subsection in Real Property evaluating whether the submitted leases contained required language contained in 10 NYCRR 1004.5(b)(9). In support of this claim, HHE states that another applicant, Citiva Medical

(Citiva), received a score of 3 points for this subsection. Having reviewed the scoring criteria, however, I fail to see how an applicant could have exceeded this criterion with a better than average level of performance when the item being rated was whether the leases contained language required by the regulations. If the language is in the leases, then the applicant should earn 2 points. HHE has not shown that its application or Citiva's merited anything greater than 2 points which are awarded when an applicant has met the minimum criteria for the item being evaluated. Although this hearing is not a review of the Citiva's application, I note that Citiva's application would still rank higher than HHE's if the one additional point earned in this subsection were deducted from its overall score.

HHE contended that it should have received additional points in the subject area of Product Manufacturing. This area was graded independently by a pair of scientists using the criteria's specific rating scale contained in the scoring tool (Ex. 8h.). The two reviewers were David Charles Spink, Ph.D. and Kenneth M. Aldous, Ph.D. Dr. Spink has a doctorate degree in Biochemistry and more than 30 years of experience as a scientist. (Ex. 17-B.) Dr. Aldous has a doctorate degree in Analytical Chemistry and also more than 30 years of experience as a scientist. (Ex. 17-A.) HHE argues based on the testimony of its managing partner that if one reviewer credited its application with a certain number of points, the second independent reviewer must have overlooked or disregarded responsive material in its application. However, the Department designed the scoring process with two independent reviewers as a means of preventing any individual reviewer from having too great an impact on the process. As detailed below, the evidence demonstrates that these two scientists could reasonably arrive at different scores depending on their interpretation of the applicant's success in demonstrating that its application met the established criteria.

Dr. Spink and Dr. Aldous scored whether HHE's standard operating procedure (SOP) manual included a detailed description of several elements of the applicant's manufacturing facility and processes. An example where these two scientists' opinion differed can be found where they scored whether the SOP in HHE's application met the criteria for providing adequate detail that extraction is "performed only with the leaves and flowers of female marijuana plants." Dr. Aldous scored this subsection of HHE's application with 0 points meaning the detail was inadequate, but Dr. Spink scored this subsection with 1 point meaning the detail was adequate. (Ex. 8h, Ex. 14a- Manufacturing tab of HHE Scoresheet.)

In support of its argument that the SOP had sufficient detail on this criteria, HHE points to items within its application but outside its SOP manual such as a flow chart on page 378 of its application which indicates that "males" are part of the waste stream. HHE also points to an SOP regarding weekly inventory on page 589 of its application which includes male plants as discarded inventory, but the SOP states nowhere that extraction will only be performed with the leaves and flowers of female plants. As such, HHE has failed to establish that Dr. Aldous's scoring of 0 points was incorrect. To the contrary, it suggests that Dr. Spink may have given HHE's application one point for having adequate detail in its SOP when the required detail was not within the SOP as required but was merely suggested elsewhere in the application. On balance, it is more reasonable to conclude the different scores are related to differences in personal expectations of the reviewers. As such, the scoring methodology of averaging the scores of the paired reviewers with appropriately related education and experience was rational.

HHE's claim in its brief at page 22-23 that Dr. Walsh testimony on this issue was contradictory and damaged her credibility is without merit. Instead, I find that Dr. Walsh's testimony was highly credible, and Dr. Walsh's statement that HHE had failed to provide adequate

detail in its SOP regarding extraction being performed only with the female plants is entirely consistent with Dr. Walsh's statement that HHE's application contained statements elsewhere which indicated male plants were discarded at some point along the process. The criteria being scored was whether there was adequate detail in the SOP and not whether performing extraction from female plants could be inferred from statements elsewhere in the HHE's application.

HHE also argued that it's application should have received additional points in the subject area of Sales & Dispensing. This area was also graded independently by a pair of reviewers using the criteria's specific rating scale contained in the scoring tool (Ex. 8j.). The two reviewers were Dr. Quackenbush and Debra Hotaling who is a pharmacist.

An example where these two reviewers' opinion differed can be found where they scored whether HHE's policies and procedures demonstrated operation with supervision by a pharmacist at the dispensing facility at all times during business hours. Dr. Quackenbush scored this subsection of HHE's application with 2 points meaning that she felt the applicant met the minimum requirement, and Ms. Hotaling scored the subsection with 0 points meaning that she felt the applicant had not met the minimum requirement. (Ex. 8j, 14a - Sales & Dispensing tab of HHE's Scoresheet.)

In an attempt to argue that Ms. Hotaling had failed to properly credit HHE for having policies and procedures which demonstrate that a pharmacist would supervise activity at all times during business hours, HHE points to items within its application such as the Operating Plan for its Dispensary on pages 410-430 of its application, the SOP for Dispensary Retail Operation on pages 675-679 and Staffing Plans on pages 1908-1909, but none of these documents specifically state that a pharmacist will be even present at the dispensing facility at all times during business

hours. Instead, they contain statements such as “each dispensary will feature several Staff Pharmacists” or that there will be “3 full-time pharmacists.”

As such, HHE has failed to establish that Ms. Hotaling’s scoring of 0 points was incorrect. To the contrary, it suggests that Dr. Quackenbush may have given HHE’s application two points for meeting the minimum requirement when the required detail was not in the operating plan for sales and dispensing policies and procedures. On balance, it is more reasonable to conclude the different scores are related to differences in personal expectations of the reviewers. Ms. Hotaling reasonably expected HHE to include a statement that a pharmacist was present during business hours, but Dr. Quackenbush may have accepted a statement that there would be several staff pharmacists even though it’s not stated that one would be present during all operating hours. As such, the scoring methodology of averaging the scores of the paired reviewers with appropriately related education and experience was rational, and perhaps worked to HHE’s benefit.

Finally, HHE claimed that its application should have earned two additional point in the subject area of Miscellaneous Regulatory Requirements in which one of items being evaluated was whether the applicant had demonstrated that it was in the public’s interest that the registration be granted. HHE bases this assertion on a partnership which had been planned with Montefiore Medical Center for HHE’s dispensary in the Bronx. However, the consideration criteria for this item was the item was an overall evaluation of HHE’s application, Appendix A, Appendix B and all supporting attachments. (Ex. 8f.) HHE has failed to establish that its proposal to form a partnership with a hospital for its dispensary in the Bronx merits a score of 3 which would have meant an excellent rating for this item and that HHE “met or exceeded the minimum criteria for the item being evaluated by clearly demonstrating a better than average level of performance.” (Ex. 8b.)

CONCLUSION

HHE has established that the overall score of its application could be raised from 86.17 to 86.73 due to an increase in its Real Property score, but HHE has not established that the increased score would place its application's rank above the ten organizations which have been currently registered. As stated earlier, the CCA provides that the Commissioner must be satisfied that it is in the public interest to grant a registration and may consider whether the number of ROs in an area will be adequate or excessive to reasonably serve the area. At this time, the Department has registered only the ten most highly ranked applicants. In the event that the Commissioner determines that the number of RO's in an area is inadequate or it is in the public interest to grant additional registrations, HHE will have an opportunity to receive further consideration of its application when its position on the ranked list has been reached; however, the Department's decision to not register HHE as one of the initial Registered Organizations was correct.

RECOMMENDATION

Based upon the foregoing, I recommend that the Department's decision to not yet grant HHE's Registered Organization application be sustained.

Dated: Menands, New York
July 31, 2019

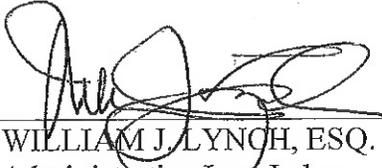

WILLIAM J. LYNCH, ESQ.
Administrative Law Judge

EXHIBIT D

RECEIVED

2016 NOV 28 PM 3:16
ALBANY COUNTY CLERK

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

-----X
VALLEY AGRICEUTICALS, LLC.

Petitioner,

SUMMONS

vs.

INDEX NO.: 03578/16

NEW YORK STATE DEPARTMENT OF HEALTH, and
HOWARD A. ZUCKER, Commissioner

Place of Trial: Albany, NY

Respondents,

The basis of venue is
Respondents' place of
business.

For a Judgment Pursuant to Article 78 of the Civil
Practice Law and Rules.

-----X
To:

New York State Department of Health
Corning Tower
Empire State Plaza
Albany, New York 12237

and

State of New York
Office of the Attorney General
Justice Building, Second Floor
Empire State Plaza
Albany, New York 12224

2016 JUN 30 AM 9:09
CONFIDENTIAL COURTS

YOU ARE HEREBY SUMMONED and required to serve upon Petitioner's attorneys
an Answer to Petitioner's Verified Article 78 Petition within twenty (20) days after the service of
this summons, exclusive of the day of service (or within thirty (30) days after the service is
complete if this summons is not personally delivered to you within the State of New York), and
in case of your failure to appear or answer, judgment will be taken against you by default for the
relief demanded in the Verified Petition pursuant to CPLR Article 78.

2/20

By: Travis Tatko / CRTB, with permission

Travis M. Tatko
Tatko Law Firm, PLLC
43 West 43rd Street, Suite 118
New York, NY 10036
Phone: (212) 804-8401

and

David J. Shlansky*
Colin R. Hagan*
Shlansky Law Group, LLP
1 Winnisimmet Street
Chelsea, MA 02150

Phone: (617) 497-7200
Fax: (866) 257-9530

Attorneys for Petitioner

** Pro hac vice forthcoming*

Dated: June 30, 2016
New York, New York

RECEIVED

2016 NOV 28 PM 3:16

ALBANY COUNTY CLERK

01-16-S17960

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

-----x
VALLEY AGRICEUTICALS, LLC,

Petitioner,

vs.

NEW YORK STATE DEPARTMENT OF HEALTH, and
HOWARD A. ZUCKER, Commissioner

Respondents,

**NOTICE OF PETITION
PURSUANT TO CPLR
ARTICLE 78**

INDEX NO: 03578/16

For a Judgment Pursuant to Article 78 of the Civil
Practice Law and Rules.

2016 JUN 30 AM 9:09

CLERK OF SUPREME COURT
ALBANY COUNTY

-----x
TO THE ABOVE NAMED RESPONDENTS:

PLEASE TAKE NOTICE that, upon the annexed Verified Petition, the undersigned shall move at the court house of the New York State Supreme Court, Albany County Courthouse, located at 16 Eagle Street, Albany, New York 12207, in the Motion Submission Part, Room 130, at 9:30 a.m. on August 5, 2016, or as soon thereafter as counsel may be heard for an Order of Judgment pursuant to Article 78 of the Civil Practice Law and Rules:

- A. Ordering the State of New York, Department of Health ("DOH") and Commissioner Howard A. Zucker, M.D., J.D. ("Commissioner Zucker) to identify any reason why Valley Agriceuticals should not have been issued a registration as a Registered Organization in the New York State Medical Marijuana Program;
- B. Ordering Commissioner Zucker and the DOH to schedule a hearing on Valley Agriceuticals's application within 30 days;
- C. Ordering Commissioner Zucker and the DOH to disclose the information requested in the FOIL request that was submitted on Valley Agriceuticals's behalf;
- D. Annuling and vacating Commissioner Zucker's and the DOH's decision to award a score or issue registration to any applicant that failed to comply with the requirements of 10 NYCRR §§ 1004.5(b)(9), 1004.6(b)(6);

- E. Annuling and vacating Commissioner Zucker's and the DOH's decision to award a score or issue registration to any applicant that was insufficiently capitalized or lacks the requisite financial resources to develop and operate a medical marijuana cultivation facility and one or more dispensaries;
- F. Granting Petitioner its costs and disbursements of this action; and
- G. Granting such other and further relief as the Court deems just and proper.

PLEASE TAKE FURTHER NOTICE that, Pursuant to CPLR 7804(c), an Answer and any supporting papers must be served on the undersigned no later than five (5) days before the return date set forth above.

Respectfully Submitted,

VALLEY AGRICEUTICALS, LLC

By its attorneys,

By: Travis Tatko / CKA, with permission
Travis M. Tatko
Tatko Law Firm, PLLC
43 West 43rd Street, Suite 118
New York, NY 10036
Phone: (212) 804-8401

and

David J. Shlansky*
Colin R. Hagan*
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Chelsea, MA 02150
Phone: (617) 497-7200
Fax: (866) 257-9530

Attorneys for Petitioner

** Pro hac vice forthcoming*

Dated: June 30, 2016
New York, New York

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

RECEIVED

2016 NOV 28 PM 3: 16
ALBANY COUNTY CLERK



-----X
VALLEY AGRICEUTICALS, LLC,

Petitioner,

VERIFIED PETITION

vs.

INDEX NO.: 03578/16

NEW YORK STATE DEPARTMENT OF HEALTH, and
HOWARD A. ZUCKER, Commissioner

ORAL ARGUMENT
REQUESTED

Respondents,

For a Judgment Pursuant to Article 78 of the Civil
Practice Law and Rules.

-----X
Petitioner Valley Agriceuticals, LLC ("Valley Agriceuticals" or "Petitioner"), for its
verified Petition for judgment pursuant to Article 78 of the New York Civil Practice Law and
Rules ("CPLR"), by and through its undersigned attorneys, hereby states as follows:

INTRODUCTION

1. This proceeding seeks to require the New York State Department of Health ("DOH") and Commissioner Howard A. Zucker, M.D., J.D. ("Commissioner Zucker") to schedule a hearing on Petitioner's Application for Registration as a Registered Organization in the New York State Medical Marijuana Program (the "Application"), which it submitted to the New York Department of Health, Bureau of Narcotic Enforcement, Medical Marijuana Program (the "DOH") on June 5, 2015, pursuant to Public Health Law § 3365 and the implementing regulations for the Compassionate Care Act, 10 NYCRR §§ 1004.1, *et seq.* (the "Regulations"). This proceeding also seeks to: (a) require the DOH and Commissioner Zucker to identify any reason why Valley Agriceuticals should not have been issued a registration; (b) disclose certain information requested on behalf of Valley Agriceuticals pursuant to the New York Freedom of

Information Law; (c) annul and vacate Commissioner Zucker's and DOH's decision to award a score or issue registration to any applicant that failed to comply with the requirements of 10 NYCRR §§ 1004.5(b)(9), 1004.6(b)(6); and (d) annul and vacate Commissioner Zucker's and the DOH's decision to award a score or issue registration to any applicant that was insufficiently capitalized or lacks the requisite financial resources to develop and operate a medical marijuana cultivation facility and one or more dispensaries.

2. In June 2014, the New York legislature passed the Compassionate Care Act (the "Act"), authorizing the cultivation, distribution, and prescription of medical marijuana for use in treating certain debilitating illnesses. Governor Andrew M. Cuomo signed the Act into law on July 7, 2014.

3. Commissioner Zucker is directed in the Act to perform certain functions related to the medical marijuana program.

4. Valley Agriceuticals is a New York limited liability company comprised of recognized industry leaders in business, finance, research, and medicine. Valley Agriceuticals was formed to pursue a medical cannabis license from the DOH and to deliver a science-based and patient-focused series of medical cannabis products in New York.

5. In support of its Application, Valley Agriceuticals attracted local approval for a cultivation facility in Wallkill, New York; developed a first-of-its-kind partnership with Teva Pharmaceuticals Industries LTD (the largest manufacturer of generic drugs in the world) to bring scientific and pharmaceutical expertise to the medical cannabis industry in New York; and assembled a team of professionals and experts in a variety of fields, including in the areas of palliative care, medical marijuana cultivation, security, regulation of pharmacies and pharmaceuticals, supply chain design, and inventory management and delivery.

6. Valley Agriceuticals acquired ownership of property suitable for a cultivation facility located at 173 Dosen Road, Middletown, NY 10940.

7. Valley Agriceuticals also secured leases for four dispensary locations in Westchester, Manhattan, Rochester, and Albany, New York.

8. Additionally, Valley Agriceuticals began construction of a state-of-the-art cultivation facility that integrated the manufacturing needs of a top medical marijuana cultivation facility, seamless integration into the community aesthetic, and preservation of farmland and open space consistent with local community goals.

9. Although Valley Agriceuticals was widely recognized to have one of the strongest teams and applications, it received an eighth-place score, based on a scoring and weighting system that the DOH developed and which lacks any basis in the Act or the Regulations.

10. The DOH never publicly proposed any such scoring and weighting system, and despite a New York Freedom of Information Law ("FOIL") request on behalf of Valley Agriceuticals, has failed to disclose how it developed such a scoring and weighting system (especially without the opportunity for public comment thereon) and how it scored the applicants on the various criteria set forth in the Act and the Regulations.

11. Instead, the DOH: (a) developed and implemented a scoring and weighting system under the cover of darkness and without public comment; (b) notified Valley Agriceuticals that it had not received a sufficient score to be issued a registration, but without identifying any factor or criterion on which more information was required or where Valley Agriceuticals had failed to comply with the Act or Regulations, and nevertheless informed Valley Agriceuticals that it must request a hearing within 30 days; (c) has failed to schedule a hearing for nearly a year after Valley Agriceuticals requested a hearing; (d) has failed to provide

Valley Agriceuticals, or any other applicant, with information regarding the scoring and weighting system or the details of its evaluation of the 43 applicants; and (e) awarded a higher score, and issued registration to, one or more applicants that failed to comply with the Act or Regulations.

12. Accordingly, the DOH has: (a) failed to perform duties imposed on it by statute; (b) has acted in excess of its statutory authority or any delegated discretion; and (c) has rendered decisions that are affected by errors of law, are arbitrary and capricious, and are an abuse of discretion.

PARTIES

13. Petitioner Valley Agriceuticals, LLC, is a New York limited liability company comprised of recognized industry leaders in business, finance, research, and medicine. It has a principal place of business located at 2500 Westchester Ave., Purchase, New York 10577.

14. Respondent State of New York Department of Health is an agency of the State of New York, with a principal place of business located at Corning Tower, Empire State Plaza, Albany, New York 12237.

15. Respondent Commissioner Howard A. Zucker, M.D., J.D., is Commissioner of Health for the State of New York, and is a party to this action in his official capacity. Commissioner Zucker has a principal place of business located at Corning Tower, Empire State Plaza, Albany, New York 12237.

JURISDICTION

16. This Court has jurisdiction pursuant to CPLR § 7801, *et seq.*, to review the action or inaction of state agencies and their officers.

17. Venue in the County of Albany is proper pursuant to CPLR §§ 505(a) and 506(a)

and (b) because the actions or inactions described in this Petition occurred primarily in the County of Albany, and the Petition names as Respondents state agencies and state officials with a principal place of business in the County of Albany.

FACTS

I. The Compassionate Care Act and its Implementing Regulations.

18. The Act provides that:

The commissioner shall register no more than five registered organizations that manufacture medical marihuana with no more than four dispensing sites wholly owned and operated by such registered organization. The commissioner shall ensure that such registered organizations and dispensing sites are geographically distributed across the state. The commission may register additional registered organizations.

PHL § 3365(9).

19. The Act further specifies the information that must be included in an application and provides that “[t]he commissioner shall grant a registration or amendment to a registration if he or she is satisfied that” certain enumerated conditions have been met by the applicant. PHL § 3365(3).

20. The Act does not provide a procedure for challenging the registration or failure to register an applicant. *See generally*, PHL § 3365.

21. However, the Act provides that “[i]f the commissioner is not satisfied that an applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required. Within thirty days of the receipt of such notification, the applicant may submit additional material to the commissioner or demand a hearing, or both.” PHL § 3365(3)(b).

22. The Regulations adopt this statutory requirement, verbatim. *See* 10 NYCRR § 1004.6(d).

23. Separately, the Act provides that, in connection with an application for renewal of an existing registration, an applicant may demand a hearing and “the commissioner shall fix a date as soon as reasonably practicable.” PHL § 3365(3)(e).

24. The DOH Medical Marijuana Program website reports that it began accepting applications on April 27, 2015, and that the deadline to submit applications was June 5, 2015. *See* https://www.health.ny.gov/regulations/medical_marijuana/application/applications.htm; *See also* New York, Department of Health, Medical Marijuana Program, Application for Registration as a Registered Organization – Questions and Answers.

25. The DOH Medical Marijuana Program website further avers that the DOH “evaluated all completed applications received on or before the deadline in accordance with the criteria set forth in PHL § 3365 and Title 10 of the New York Code of Rules and Regulations (NYCRR) §§ 1004.5 and 1004.6.”

II. Valley Agriceuticals’s Application and Request for a Hearing.

26. On June 5, 2015, Valley Agriceuticals submitted its Application to the DOH, which application comprised more than 2,000 pages and included the requisite Form DOH-5138 and all requisite attachments, appendices, and supporting documentation.

27. The DOH received 43 applications for registration.

28. The DOH Medical Marijuana Program website avers that “[t]he evaluation process considered information provided by applicants that responded to requirements of PHL § 3365 and 10 NYCRR §§ 1004.5 and 1004.6.” The DOH further avers that “[a] combination of weighted scored criteria and other criteria were assigned to a number of areas and evaluated.”

29. Neither the Act nor the Regulations provide for any scoring, nor do they provide any guidance concerning how any criterion should be scored or weighted.

30. On or about July 31, 2015, the DOH released the scores for the 43 applicants, including Valley Agriceuticals.
31. Valley Agriceuticals scored eighth, with a score of 89.49.
32. The next highest score was 90.23.
33. On July 31, 2015, the DOH sent a letter to Valley Agriceuticals to notify it that it did not receive one of the top 5 highest scores and, therefore, would not be registered.
34. The July 31, 2015, letter purported to invoke the provisions of PHL § 3365(3)(b) and purported to give Valley Agriceuticals 30 days therefrom to request a hearing.
35. However, the July 31, 2015, letter did not notify Valley Agriceuticals of “those factors upon which further evidence is required,” pursuant to PHL § 3365(3)(b) and 10 NYCRR § 1004.6(d).
36. On August 3, 2015, Valley Agriceuticals submitted a formal request for a hearing, and the DOH acknowledged receipt thereof.
37. However, as of the date of this filing, the DOH has not scheduled the required hearing.
38. On or about August 27, 2015, Erik Holling (“Mr. Holling”), President of Valley Agriceuticals, spoke with Rick Zahnleuter, Esq. (“Mr. Zahnleuter”), who at the time was Acting General Counsel for the DOH. Mr. Zahnleuter informed Mr. Holling that the DOH was working on a schedule for hearings and would notify Valley Agriceuticals of the date for its hearing by mid-September 2015. Mr. Zahnleuter further informed Mr. Holling that the hearing would be scheduled for a date in October 2015.
39. On or about October 22, 2015, Mr. Holling again spoke with a member of the DOH Office of General Counsel, who informed him that no hearings had been scheduled at that

time, despite the fact that approximately three months had passed since Valley Agriceuticals requested a hearing. Mr. Holling was informed at that time that the DOH expected to schedule a hearing in the following few weeks. However, no such hearing was ever scheduled.

III. Valley Agriceuticals and the DOH Enter into a Tolling Agreement.

40. On or about November 30, 2015, in view of the fact that the DOH had failed to schedule the required hearing, the DOH and Valley Agriceuticals entered into a tolling agreement (the "Agreement") to toll any deadline for Valley Agriceuticals to commence a proceeding under Article 78. A true and correct copy of the Agreement is submitted herewith at Exhibit A.

41. Valley Agriceuticals was informed by counsel for the DOH that the DOH would not negotiate the tolling agreement that it had proposed.

42. The Agreement acknowledged that Valley Agriceuticals had requested a hearing pursuant to PHL § 3365(3)(b) after receiving notice from the DOH that it had not been selected for registration.

43. The Agreement tolled the time for Valley Agriceuticals to commence a proceeding under Article 78. However, the parties specifically agreed that "by entering into this Agreement, the Applicant is not waiving its right to commence and/or continue legal action against DOH concerning the July 31, 2015 Letter, or any other determinations made by DOH in connection with the Application, or any review and/or appeal, administratively or otherwise, of the Application." Ex. A, Agreement § 3.

44. The Agreement tolled the time for Valley Agriceuticals to commence a proceeding under Article 78 until March 1, 2016.

45. The Agreement to toll the deadline for Valley Agriceuticals to commence a

proceeding under Article 78 was “[i]n consideration of [Valley Agriceuticals’] forbearance from commencing an Article 78 Proceeding concerning the July 31, 2015 Letter . . .” Ex. A, Agreement § 1.

46. On February 26, 2016, one business day prior to the expiration of the Agreement, Michael Bass, Esq. (“Mr. Bass”), an attorney for the DOH, wrote to Mr. Holling offering to extend the Agreement to July 1, 2016.

47. To date, the DOH has still not set a hearing date pursuant to Valley Agriceuticals’s *bona fide* request.

48. Valley Agriceuticals has been informed by agents for other applicants that the DOH does not intend to provide applicants with an individual hearing, pursuant to each applicant’s request, but instead proposes to hold a group hearing.

49. Thereafter, Valley Agriceuticals and the DOH agreed to extend the Agreement to toll any deadline to commence a proceeding under Article 78 to July 1, 2016. A true and correct copy of the agreement to further extend the deadline is submitted herewith at Exhibit B.

IV. Valley Agriceuticals Learns of Infirmities in the DOH Review Process and Requests Information.

50. Following its receipt of notice that it would not be issued a registration, Valley Agriceuticals began engaging in discussions with other applicants and was approached by certain applicants, including those that received a higher score or that received a registration, for advice and to inquire about opportunities to collaborate.

51. This was in part because Valley Agriceuticals was widely recognized, including by other applicants, to have assembled and submitted one of the strongest applications and teams of any applicant.

52. Valley Agriceuticals has engaged in discussions with other applicants, including

some who received registration, and is informed that the DOH might have improperly scored or registered certain registered companies that purportedly received the top five highest scores.

53. In particular, Valley Agriceuticals is informed and aware that certain applicants and registered entities that purportedly scored higher than Valley Agriceuticals lacked the requisite ownership or leasehold interests in real estate sufficient for a cultivation or distribution facility, pursuant to, *inter alia*, 10 NYCRR §§ 1004.5(b)(9), 1004.6(b)(6).

54. The DOH initially indicated to applicants, including Valley Agriceuticals, that factors including access to suitable real estate and security were among the most important factors. However, the weight given to these factors appears to have been minimized in the final selection process, as evidenced by the fact that certain applicants that lacked any access to real estate, whether in an ownership or leasehold interest, were awarded registration.

55. Additionally, Valley Agriceuticals is informed and aware that certain applicants and registered entities that purportedly scored higher than Valley Agriceuticals lacked the requisite capitalization or financial resources to undertake the actions necessary to construct and operate a cultivation facility and one or more distribution facilities. Valley Agriceuticals is further informed and aware that one or more such entities are on the brink of insolvency or are seeking to be acquired in light of their dire financial positions.

56. Upon information and belief, the DOH and Commissioner Zucker awarded registration to certain applicants based on political considerations or other impermissible factors instead of the criteria set forth in the governing statute or implementing regulations.

57. Upon further information and belief, certain applicants were apparently awarded registration because the applicants were all female or because their applications indicated that they were working with large or politically popular contractors.

58. In light of this information, and given that Valley Agriceuticals had received a score that placed eighth out of the total of 43 applicants; had received a letter from the DOH notifying it that it did not receive one of the top 5 scores and, therefore, would not be registered; was not informed by the DOH what, if any, "factors upon which further evidence is required," pursuant to PHL § 3365(3)(b) and 10 NYCRR § 1004.6(d); and had not received a hearing after several months, on September 24, 2015, Valley Agriceuticals, by and through its counsel, requested information from the DOH pursuant to the New York Freedom of Information Law.

59. The FOIL request sought information related to, *inter alia*:
- a. Program records relating to the DOH's operational requirements, plan, and guidelines for the Program.
 - b. The applications for several registrants and applicants (which at that time had not been published).
 - c. Records related to: (a) the creation, development, establishment, and approval of the selection guidelines, scoring criteria, and definitions related to the scoring criteria; (b) the names and qualifications of all persons who were involved with, responsible for, or approved the selection guidelines, scoring criteria, and definitions related to the scoring criteria; and (c) the date(s) of the creation, development, establishment, and approval of the selection guidelines, scoring criteria, and definitions related to the scoring criteria, including, without limitation, all signature and approval dates related to the foregoing categories.
 - d. Records of the Application approval and selection guidelines and the process for establishing the evaluation scored criteria, the raw score, the sub-scores, the conversion factor and the weighted score, including any votes, consents and approvals by any of the DOH Parties and any other state agency or state official.
 - e. Records of the definitions, instructions, guidelines, formulas, and processes for evaluating the Applications through primary, raw, and any other sub-scoring systems, utilizing the "evaluation tool," applying points under the evaluation scored criteria, the raw score, the conversion factor, the weighted score and "other evaluation criteria."
 - f. Records that indicate the standards and guidelines for the composition of the evaluation committee, the number of members required to be on the

committee, the number of committee members that served at any time during the review and evaluation of the Applications, and the requirements and expertise necessary to become a member of the evaluation committee.

- g. Records indicating the name and qualifications of each member of the evaluation committee that served at any time during the evaluation of the Applications and the time period during which such member served.
- h. Records indicating whether each Application was fully reviewed, evaluated and scored by each member of the evaluation committee or assigned to separate members for individual evaluation and scoring or partial review, the names of each member that reviewed and scored each Application or any section of an Application, including indication of which section was scored by such member, and whether any further review of the Applications was made by any of the other DOH Parties, any other state agency, or state official, along with the name of such DOH Party, agency or official and the date of such review.
- i. Records evidencing all research or review outside of the Application conducted at any stage during or prior to the Application process by the DOH Parties, including, without limitation, the evaluation committee or any individual member of the committee.
- j. Records evidencing minutes and notes of any meetings of each of the DOH Parties, including any executive meetings, in respect of the Program and the evaluation, review and consideration of the Applications, and the final determination and selection of the registered organizations.
- k. Records of the DOH's final determination and selection of the registered organizations, including the final determination report, records indicating which DOH Parties, state agencies and state officials were involved in the final registered organization selection, approval, validation or sign-off, and the date(s) of involvement of each, along with records evidencing any votes, consents and approvals of any of the DOH Parties and any other state agency or state official relating to the Application evaluation, final determination, and selection process.
- l. Records evidencing correspondence between the DOH, any New York State agency or any state agency outside of the State of New York regarding the evaluation, assessment, previous experience of or relating to any of the Ten Applicants.

60. Despite the passage of nearly 10 months since the FOIL request was made, the DOH has still failed to produce a single record in response.

61. Instead, the DOH purported to extend its timeline for processing the FOIL request on at least three occasions.

62. On September 24, 2015, the DOH responded to the FOIL request, indicating that a determination on the request would be made within 20 business days.

63. On October 30, 2015, the DOH Records Access Office sent a letter in response to the request, indicating that it was continuing to process the FOIL request and would complete its process by December 15, 2015.

64. However, on December 15, 2015, the DOH Records Access Office wrote another letter indicating that it was continuing to process the FOIL request and would complete its process by January 29, 2016.

65. In or around January or February 2016, counsel for Valley Agriceuticals spoke with counsel for the DOH regarding the FOIL request, and was told that a response was in process, but the DOH did not respond with any records.

66. Most recently, on June 1, 2016, nearly 10 months after the FOIL request was made, the DOH Records Access Office has still not produced any records and indicated that it anticipates completing its review process by July 14, 2016.

67. To date, the DOH has not produced any records in response to the FOIL request.

68. Valley Agriceuticals has been informed by agents of other applicants that they have made FOIL requests and also have not received any production of records.

69. In general, Valley Agriceuticals is informed and believes that there is growing discontent among applicants and the general public regarding the state of New York's medical marijuana program and how it has been administered.

70. Specifically, in or around November 2015, Governor Cuomo signed a bill to

provide emergency access to medical marijuana for eligible patients in New York, in light of the DOH's failure to implement the New York medical marijuana program timely.

71. Although Valley Agriceuticals indicated to the DOH that it was ready, willing, and able to move forward, if approved, especially in light of the emergent need for medical marijuana in New York, upon information and belief, the DOH did not move forward to implement the requirements of the emergency legislation.

72. Numerous patients and advocates have expressed concern that planned dispensaries will not open as expected or

**FIRST CAUSE OF ACTION
CPLR §§ 7803(1), (2)**

73. Petitioner repeats and re-alleges the allegations in the foregoing paragraphs as if fully set forth herein.

74. The Act and Regulations require the DOH to identify any "factors upon which further evidence is required" for any applicant that does not receive registration. PHL § 3365(3)(b); 10 NYCRR § 1004.6(d).

75. On July 31, 2015, the DOH informed Valley Agriceuticals that it did not receive one of the top five highest scores and, therefore, would not receive registration.

76. However, the DOH failed to identify any "factors upon which further evidence is required."

77. For all of the above reasons, the DOH failed to perform a duty imposed by statute.

**SECOND CAUSE OF ACTION
CPLR §§ 7803(1), (2)**

78. Petitioner repeats and re-alleges the allegations in the foregoing paragraphs as if fully set forth herein.

79. The Act and Regulations permit an applicant to demand a hearing within thirty days of receiving notification that the “commissioner is not satisfied that the applicant should be issued a registration.” PHL § 3365(3)(b); 10 NYCRR § 1004.6(d).

80. On July 31, 2015, the DOH notified Valley Agriceuticals by letter that it had not received one of the top five scores and, therefore, would not be issued a registration.

81. On August 3, 2015, Valley Agriceuticals requested a hearing.

82. The DOH acknowledged receipt of Valley Agriceuticals’s request for a hearing.

83. Although nearly a year has passed since DOH notified Valley Agriceuticals that it would not receive registration and Valley Agriceuticals timely requested a hearing, the DOH has not scheduled a hearing.

84. For all of the above reasons, the DOH’s refusal to schedule a hearing for Valley Agriceuticals constitutes a failure to perform a duty imposed by statute.

**THIRD CAUSE OF ACTION
CPLR §§ 7803(2), (3)**

85. Petitioner repeats and re-alleges the allegations in the foregoing paragraphs as if fully set forth herein.

86. PHL § 3365 and 10 NYCRR §§ 1004.1, *et seq.*, govern the application process for registration as a registered organization to manufacture and dispense approved medical marijuana products in New York pursuant to the DOH’s Medical Marijuana Program.

87. The Commissioner Zucker and the DOH devised a scoring and weighting procedure for its review of Medical Marijuana Program applications.

88. Neither the Act nor the Regulations provide for any such scoring or weighting of the application and selection criteria.

89. The DOH did not propose any Regulations that would address scoring or

weighting of the application and selection criteria.

90. To date, despite a FOIL request on behalf of Valley Agriceuticals, the DOH has failed to provide any information concerning the development of its scoring and weighting procedure.

91. For all of the above reasons, the Commissioner's DOH's use of a scoring and weighting procedure is in excess of its statutory authority or any discretion delegated to it by statute.

FOURTH CAUSE OF ACTION
CPLR §§ 7803(2), (3)

92. Petitioner repeats and re-alleges the allegations in the foregoing paragraphs as if fully set forth herein.

93. PHL § 3365 and 10 NYCRR §§ 1004.1, *et seq.*, set forth the information that an applicant must include in an application and that the DOH must consider in connection with any review of an application.

94. Valley Agriceuticals submitted an application that included all of the required information and any other information requested by the DOH.

95. The DOH awarded a higher score than Valley Agriceuticals received, and even registration, to one or more applicants that lacked the requisite ownership or leasehold interests in real estate sufficient for a cultivation or distribution facility, pursuant to, *inter alia*, 10 NYCRR §§ 1004.5(b)(9), 1004.6(b)(6).

96. In addition, the DOH awarded a higher score than Valley Agriceuticals received, and even registration, to one or more applicants that lacked sufficient capitalization or financial resources to undertake the actions necessary to construct and operate a cultivation facility and one or more distribution facilities.

TOLLING AND EXTENSION AGREEMENT

This Tolling and Extension Agreement ("Agreement") is entered into and made effective this 30th day of November, 2015 by and between New York State Department of Health ("DOH") and Valley Agricultural (the "Applicant"), which requested a hearing, pursuant to Public Health Law § 3365(3)(b), after receiving notice from DOH that it was not selected for registration as a registered organization to manufacture and dispense approved medical marijuana products in New York State.

WHEREAS, the Applicant has applied for registration as a registered organization in New York State's Medical Marijuana Program (the "Application"); and

WHEREAS, by letter dated July 31, 2015 (the "Letter"), DOH has informed the Applicant that its application did not score within the top five applicants, and, therefore, was not eligible for one of the five registrations that the Department selected on July 31, 2015; and

WHEREAS, the July 31, 2015 Letter also provided that, pursuant to Public Health Law § 3365(3)(b), each Applicant had (30) days from receipt of the notification to request a hearing; and

WHEREAS, the Applicant has requested a hearing; and

WHEREAS, the Applicant may only have until November 30, 2015 to commence a special proceeding challenging whether the July 31, 2015 Letter constitutes a final and binding determination by the DOH; and

WHEREAS, DOH and the Applicant wish to enter into an agreement to toll and extend the statute of limitations for commencing an Article 78 Proceeding in contemplation of the possibility that the Letter is held to constitute a final and binding determination by DOH.

NOW THEREFORE, in consideration of the promises made herein and other good and valuable consideration, the receipt of which is hereby acknowledged, DOH and the Applicant, intending to be legally bound, hereby agree that:

1. In consideration of the Applicant's forbearance from commencing an Article 78 Proceeding concerning the July 31, 2015 Letter at this time, the time period during which the Applicant may commence and/or continue legal action with respect to the July 31, 2015 Letter, including but not limited to commencing an Article 78 Proceeding concerning the July 31, 2015 Letter (whether determined by a statute of limitations, laches, estoppel or otherwise), shall be tolled and is hereby extended until March 1, 2016 (the "Expiration Date").

2. This Expiration Date may be extended by written agreement between DOH and the Applicant.

3. DOH and the Applicant further agree that by entering into this Agreement, the Applicant is not waiving its right to commence and/or continue legal action against DOH concerning the July 31, 2015 Letter, or any other determinations made by DOH in connection with the Application, or any review and/or appeal, administratively or otherwise, of the Application.

4. DOH reserves the right to claim that the statute of limitations for an Article 78 Proceeding concerning the July 31, 2015 Letter may not start to run until a hearing decision is rendered and administrative remedies are otherwise exhausted. Further, DOH is under no obligation to commence hearings prior to the Expiration Date of this agreement.

5. The Applicant's representative who has executed this Agreement hereby certifies that he or she has been duly authorized to do so by his or her respective client, and the Applicant intends, by its representative having signed this Agreement on the Applicant's behalf, to be bound by the terms of this Agreement.

6. This Agreement shall be construed under and governed, by the laws of the State of New York.

7. This Agreement contains the entire agreement between DOH and the Applicant relating to the subject matter contained in this Agreement. Modifications to this Agreement shall be effective only if in writing and executed by both DOH and the Applicant executing this Agreement.

8. This agreement may be signed in counterparts. Copies, facsimiles and electronic signatures shall be deemed as good, and as binding, as originals.

IN WITNESS WHEREOF, the undersigned have executed this Agreement as of the date first set forth above,

New York State Department of Health

Michael G. Bass

By: Michael G. Bass

Date: November 30, 2015

STATE OF NEW YORK)
COUNTY OF Albany) ss.:

On November 30th, 2015, before me, the undersigned, personally appeared Michael G. Bass, personally known to me or proved to me on the basis of satisfactory evidence to be the individual whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his capacity, individually, and as authorized representative of NEW YORK STATE DEPARTMENT OF HEALTH and that by his signature on the instrument, the individual, or the person upon behalf of which the individual acted, executed the instrument.

Justin D. Pfeiffer
NOTARY PUBLIC

JUSTIN D. PFEIFFER
NOTARY PUBLIC, State of New York
Lic. # 02PF6213787
Qualified in Albany County
My Commission Expires 11/16/2017

[Handwritten mark]

Valley Agricultural

~~By: _____~~

Rhode Island
STATE OF NEW YORK)
COUNTY OF *Newport*) ss:

On *November 30th*, 2015, before me, the undersigned, personally appeared *Erik E. Hollis*, personally known to me or proved to me on the basis of satisfactory evidence to be the individual(s) whose name(s) is (are) subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/hers/their capacity(ies), individually, and as authorized representative of Valley Agricultural and that by his/hers/their signature(s) on this instrument, the individual(s), or the person upon behalf of which the individual(s) acted, executed the instrument.

Ryan Demello

NOTARY PUBLIC

WHEREAS, the July 31, 2015 Letter also provided that, pursuant to Public Health Law § 2385(3)(b), each Applicant had (30) days from receipt of the notification to request a hearing; and

WHEREAS, the Applicant has requested a hearing; and

WHEREAS, the Applicant may only have until November 30, 2015 to commence a special proceeding challenging whether the July 31, 2015 Letter constitutes a final and binding determination

1. In consideration of the Applicant's forbearance from commencing an Article 78 Proceeding concerning the July 31, 2015 Letter at this time, the time period during which the Applicant may commence and/or continue legal action with respect to the July 31, 2015 Letter, including but not limited to commencing an Article 78 Proceeding concerning the July 31, 2015 Letter (whether determined by a statute of limitations, laches, estoppel or otherwise), shall be tolled and is hereby extended until March 1, 2016 (the "Expiration Date").

2. This Expiration Date may be extended by written agreement between DOH and the Applicant.

3. DOH and the Applicant further agree that by entering into this Agreement the Applicant is not waiving its right to commence and/or continue legal action against DOH concerning the July 31, 2015 Letter, or any other determinations made by DOH in connection with the Application, or any review and/or appeal, administratively or otherwise, of the Application.

4. DOH reserves the right to claim that the statute of limitations for an Article 78 Proceeding concerning the July 31, 2015 Letter may not start to run until a hearing decision is rendered and administrative remedies are otherwise exhausted. Further, DOH is under no obligation to commence hearings prior to the Expiration Date of this agreement.

[Handwritten signature]

Exhibit B

March 1, 2016, Tolling Agreement

Please see attached.

AMENDMENT TO TOLLING AND EXTENSION AGREEMENT

WHEREAS, by letter dated July 31, 2015 ("July 31, 2015 Letter"), the New York State Department of Health ("DOH") informed Valley Agriceuticals (the "Applicant") that the Applicant (1) was not eligible to become one of the five registered organizations to manufacture and dispense medical marijuana products in New York State; and (2) had 30 days from receipt of the notification to request a hearing; and

WHEREAS, on November 30, 2015, DOH and the Applicant entered into a Tolling and Extension Agreement that tolled and extended the time period during which the Applicant may commence and/or continue legal action with respect to the July 31, 2015 Letter, including commencing an Article 7B (of the New York Civil Practice Law and Rules) proceeding concerning the July 31, 2015 Letter, until March 1, 2016;

WHEREAS, DOH and the Applicant wish to amend the Tolling and Extension Agreement,

NOW THEREFORE, it is hereby stipulated and agreed that:

All terms, provisions, and defined terms in the Tolling and Extension Agreement shall remain in effect, and have the same meaning herein, except as amended hereby.

The paragraph that is labeled "1" on the Tolling and Extension Agreement is amended to provide as follows:

1. In consideration of the Applicant's forbearance from commencing an Article 7B Proceeding concerning the July 31, 2015 Letter at this time, the time period during which the Applicant may commence and/or continue legal action with respect to the July 31, 2015 Letter, including but not limited to commencing an Article 7B Proceeding concerning the July 31, 2015 Letter (whether determined by a statute of limitations, laches, estoppel or otherwise), shall be tolled and is hereby extended until July 1, 2016 the "Expiration Date".

DOH reserves the right to claim that the statute of limitations for an Article 7B Proceeding concerning the July 31, 2015 Letter may not start to run until a hearing decision is rendered and administrative remedies are otherwise exhausted. Further, DOH is under no obligation to commence hearings prior to the Expiration Date of this Amendment to Tolling and Extension Agreement.

WHEREFORE, DOH and the Applicant agreed to, and accepted, this Amendment to the Tolling and Extension Agreement as of the dates indicated below.

RECEIVED

2016 NOV 28 PM 3:17

ALBANY COUNTY CLERK

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

VALLEY AGRICEUTICALS, LLC,

Petitioner,

VERIFICATION

vs.

INDEX NO.:

NEW YORK STATE DEPARTMENT OF HEALTH,

Respondent,

For a Judgment Pursuant to Article 78 of the Civil
Practice Law and Rules.

STATE OF RHODE ISLAND)
) ss.
COUNTY OF NEWPORT)

ERIK HOLLING, being duly sworn, deposes and says:

I am President and an official representative of Valley Agriceuticals, LLC. I have reviewed the annexed Verified Petition and know its contents. The information contained in the Verified Petition is true to the best of my knowledge, except as to matters stated to be alleged upon information and belief, and as to those matters, I believe them to be true.

Erik Holling

Sworn to me this 29 day of June 2016

Notary Public
758350 Exp. 9/28/19

RECEIVED

2016 NOV 28 PM 3: 18
ALBANY COUNTY CLERK

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF ALBANY

-----X
VALLEY AGRICEUTICALS, LLC,

Petitioner,

vs.

NEW YORK STATE DEPARTMENT OF HEALTH, and
HOWARD A. ZUCKER, Commissioner

Respondents,

For a Judgment Pursuant to Article 78 of the Civil
Practice Law and Rules.

INDEX NO. 3578-16

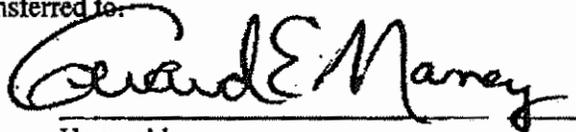
**ORDER FOR ADMISSION
PRO HAC VICE**

-----X
THIS MATTER, having been presented to the Court by Travis M. Tatko, Esq., attorney for the Petitioner, upon motion for an Order pursuant to 22 NYCRR § 602.2(a) granting *pro hac vice* admission to Colin R. Hagan, Esq., as counsel for the Petitioner, and the Court having reviewed and considered with due deliberation the Notice of Motion for Admission *Pro Hac Vice* of Attorney Hagan, his Affidavit, and his Certificate of Admission and Good Standing from the Commonwealth of Massachusetts, it is hereby:

ORDERED, that Colin R. Hagan, Esq., be admitted to practice in this department *pro hac vice*, to participate in any and all proceedings relative to the above-captioned matter, until such time as the matter has been completely resolved in this Court and any and all New York State Supreme Courts as this matter may be transferred to.

Dated:
ENTER:

9/28/16



Honorable

Gerard E. Maney



RECEIVED

2016 NOV 28 PM 3:18

STATE OF NEW YORK
SUPREME COURT CHAMBERS
30 Clinton Avenue
Albany, New York 12207
(518) 285-8600

GERARD E. MANEY
ACTING SUPREME COURT JUSTICE

September 28, 2016

Colin R. Hagan, Esq.
Shlansky Law Group LLP
1 Winnisimmet Street
Chelsea, MA 02150

Travis M. Tatko, Esq.
Tatko Law Firm, PLLC
43 West 43rd Street, Suite 118
New York NY 10036

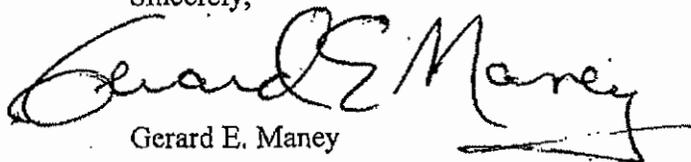
Michael G. McCartin, Esq.
Assistant Attorney General
Office of the Attorney General, State of New York
The Capitol
Albany, NY 12224-0341

Re: Valley Agriceuticals v NYS Department of Health and Howard A. Zucker, Commissioner
Albany Supreme Court Index No. 3578-16

Dear Counselors:

The motion for admission of Mr. Hagan *pro hac vice* has been granted. The Court also grants the request and will hold this Article 78 matter in abeyance for six months or until March 28, 2017. If necessary, a request for an further extension may be made by letter application at that time.

Sincerely,


Gerard E. Maney



SHLANSKY LAW GROUP, LLP
ATTORNEYS AT LAW

RECEIVED
SEP 21 2016
ALBANY COUNTY FAMILY COURT
CHAMBERS OF JUDGE MANEY

September 20, 2016

VIA FEDEX

Hon. Gerard E. Maney
Acting Supreme Court Justice
Albany County Family Court
30 Clinton Avenue
Albany, NY 12207

RECEIVED
2016 NOV 28 PM 3:18
ALBANY COUNTY CLERK

Re: Valley Agriceuticals v. New York State Department of Health, and Howard A. Zucker,
Commissioner, Albany County Supreme Court, Index No. 03578-16

Dear Judge Maney:

I am counsel to Petitioner Valley Agriceuticals, LLC ("Valley"), and I write on behalf of the parties with respect to the above-referenced matter. In short, the parties request an abeyance of Valley's Article 78 Petition for review of the New York State Department of Health's ("DOH") and Commissioner Howard A. Zucker's administration of the New York State Medical Marijuana Program. The parties submit this letter jointly at the direction of law clerk Catherine Sliwinski.

Valley filed an Article 78 Petition on June 30, 2016, seeking that the Court, *inter alia*: (a) Order the DOH and Commissioner Zucker to identify any reason why Valley should not have been issued a registration as a Registered Organization in the Medical Marijuana Program; (b) Order the DOH and Commissioner Zucker to schedule a hearing on Valley's application for registration under the medical marijuana program within 30 days; (c) Order the DOH and Commissioner Zucker to disclose the information requested in Valley's FOIL request; (d) Annul and vacate the DOH's and Commissioner Zucker's decision to award a score or issue registration to any applicant that failed to comply with the requirements of 10 NYCRR §§ 1004.5(b)(9), 1004.6(b)(6); and (e) Annul and vacate the DOH's and Commissioner Zucker's decision to award a score or issue registration to any applicant that was insufficiently capitalized or that lacks the requisite financial resources to develop and operate a medical marijuana facility and one or more dispensaries. Valley also requested an oral argument on its Petition.

Since the Petition was filed, the parties have worked cooperatively with regard to scheduling and other matters, and subsequent events have occurred that warrant an opportunity for the parties to determine whether this matter can be resolved amicably. Specifically, on or about August 19, 2016, the DOH released its "Medical Use of Marijuana Under the Compassionate Care Act: Two Year Report" (the "Report"). The Report recommends that the DOH register five additional organizations in the Medical Marijuana Program through a phased approach over two years. Depending on the circumstances, the DOH's issuance of additional registrations could resolve some or all of the issues raised in Valley's Petition.

Hon. Gerard E. Maney
Acting Supreme Court Justice
Albany County Family Court

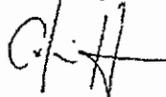
September 20, 2016

Additionally, since filing the Petition, Valley has become aware of additional facts that support the issues it has raised (and possibly give rise to other issues concerning administration of the Medical Marijuana Program). Valley intends to present these additional facts in an Amended Petition should an amicable resolution not be reached, and there is currently a stipulated deadline for Valley to file an Amended Petition by September 23, 2016.¹

In view of the possibility of an amicable resolution, and in an effort to avoid the unnecessary expenditure of the parties' or the Court's time and resources, the parties ask that the Petition be held in abeyance until September 29, 2017.² While the parties are optimistic that a resolution will be reached, they also seek to preserve their rights. Accordingly, the parties ask that the abeyance be granted such that all pending deadlines and any oral argument on the Petition is stayed until September 29, 2017, with the parties to provide a joint status report every 45 days as to whether the abeyance should be continued, altered, or terminated, and that either party may elect to terminate the abeyance at each 45-day interval.

The parties welcome the opportunity to discuss this request with the Court and appreciate Your Honor's attention to this joint request.

Sincerely,



Colin R. Hagan

cc: Travis M. Tatko, Esq. (New York counsel, by electronic mail only)
Valley Agriceuticals, LLC (by electronic mail only)
Michael G. McCartin, Esq. (by U.S. First Class mail and electronic mail)
Michael G. Bass, Esq. (by U.S. First Class mail and electronic mail)

Hon. Gerard E. Maney 09 20 16

¹ On August 24, 2016, the parties jointly requested a second adjournment of the return date for the Petition, such that Valley would file an Amended Petition by September 23, 2016, and the Respondents' Answering Papers would be due on October 21, 2016.

² While one approach might be for Valley to dismiss its Petition without prejudice, such an approach will not work under the circumstances. Specifically, the DOH issued a letter on July 31, 2015, informing Valley that it would not be awarded a registration. Pursuant to CPLR § 217, an Article 78 Petition must be commenced within 120 days from the date of the agency's final determination. Prior to Valley filing its Petition, the parties entered into two tolling agreements, ultimately tolling the deadline from November 30, 2015, to July 1, 2016.



STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
Attorney General

STATE COUNSEL DIVISION
Litigation Bureau

Writer Direct: (518) 776-2620

August 24, 2016

Mr. Charles Diamond, Chief Clerk
Office of the Clerk of the N.Y.S. Supreme Court
Albany County Courthouse
16 Eagle Street, Room 102
Albany, NY 12207

RECEIVED
2016 NOV 29 PM 3:18
ALBANY COUNTY CLERK

Attn: Deborah E. Reis

Re: Second Adjournment Request in *Valley Agriceuticals v. DOH*, New York State Supreme Court, Albany County Index No. 03578-16

Dear Mr. Diamond:

I respectfully request a second adjournment of the return date in the above-referenced matter from September 2, 2016 until October 28, 2016. The parties are presently endeavoring to resolve this matter without further litigation, a prospect that appears promising. Absent that, Petitioner will file an Amended Petition by September 23, 2016, and the Respondents' Answering Papers to it would then become due on October 21, 2016.

This is a joint request made with the consent of Petitioner's counsel.

Thank you very much for your consideration of this joint request.

Respectfully yours,
s/ Michael McCartin
Michael G. McCartin
Assistant Attorney General

cc: Travis M. Tatko, Esq.
Tatko Law Firm, PLLC
43 West 43rd Street, Ste. 118
New York, NY 10036

2016 AUG 26 AM 10:55

David J. Shansky, Esq.
Colin R. Hagan, Esq.
Shlansky Law Group, LLP
1 Winnisimmet Street
Chelsea, MA 02150



RECEIVED

2016 NOV 28 PM 3: 18
ALBANY COUNTY CLERK

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
Attorney General

STATE COUNSEL DIVISION
Litigation Bureau

Writer Direct: (518) 776-2620

July 15, 2016

Mr. Charles Diamond, Chief Clerk
Office of the Clerk of the N.Y.S. Supreme Court
Albany County Courthouse
16 Eagle Street, Room 102
Albany, NY 12207

Re: Adjournment Request in *Valley Agriceuticals v. DOH*, New York State Supreme Court,
Albany County Index No. 03578-16

Dear Mr. Diamond:

I respectfully request an adjournment of the return date in the above-referenced matter from August 5, 2016 until September 2, 2016. This is the first request in this case and it is made with the consent of petitioner's counsel.

Thank you very much for your consideration of this request.

Respectfully yours,
s/ Michael McCartin
Michael G. McCartin
Assistant Attorney General

cc: Travis M. Tatko, Esq.
Tatko Law Firm, PLLC
43 West 43rd Street, Ste. 118
New York, NY 10036

~~2016 AUG 21 PM 12: 15
COMPLAINTS~~

2016 JUL 21 PM 12: 32
COMPLAINTS



RECEIVED

2016 NOV 28 PM 3:18
ALBANY COUNTY CLERK

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

ERIC T. SCHNEIDERMAN
Attorney General

STATE COUNSEL DIVISION
Litigation Bureau

Writer Direct: (518) 776-2620

July 15, 2016

Mr. Charles Diamond, Chief Clerk
Office of the Clerk of the N.Y.S. Supreme Court
Albany County Courthouse
16 Eagle Street, Room 102
Albany, NY 12207

Re: Adjournment Request in *Valley Agriceuticals v. DOH*, New York State Supreme Court,
Albany County Index No. 03578-16

Dear Mr. Diamond:

I respectfully request an adjournment of the return date in the above-referenced matter from August 5, 2016 until September 2, 2016. This is the first request in this case and it is made with the consent of petitioner's counsel.

Thank you very much for your consideration of this request.

Respectfully yours,

s/ Michael McCartin

Michael G. McCartin
Assistant Attorney General

cc: Travis M. Tatko, Esq.
Tatko Law Firm, PLLC
43 West 43rd Street, Ste. 118
New York, NY 10036

EXHIBIT E

STATE OF NEW YORK : DEPARTMENT OF HEALTH

IN THE MATTER

OF

**NOTICE OF
HEARING**

UNSELECTED APPLICATIONS FOR REGISTRATION AS REGISTERED ORGANIZATIONS TO MANUFACTURE AND DISPENSE MEDICAL MARIHUANA UNDER NEW YORK'S COMPASSIONATE CARE ACT BY THE ORGANIZATIONS IDENTIFIED IN APPENDIX A,

Petitioners,

pursuant to Article 33 of the Public Health Law of the State of New York and Part 1004 (Chapter XIII, Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York.

TO: PETITIONERS (IDENTIFIED IN THE APPENDIX)

PLEASE TAKE NOTICE that a hearing will be held before an impartial Administrative

Law Judge on the following date, time and place:

DATE: December 5, 2017
TIME: 10:00 AM
PLACE: New York State Department of Health
Riverview Center
150 Broadway, Fifth Floor, Harvest Room
Albany, New York 12204

The hearing is being held pursuant to Section § 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"). It is being held in response to the

Petitioners' letters to the New York State Department of Health ("the Department") requesting a public hearing to challenge the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR § 1004.6(b) for the purpose of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana.

The Department's decisions to not select the Petitioners for registration as one of the five initial registered organizations, as authorized pursuant to PHL § 3365(9), are based on the Department's determinations, pursuant to PHL § 3365(3) and 10 NYCRR § 1004.6, that five other organizations submitted an application that was superior to that submitted by each of the Petitioners, in that the application better demonstrated the organization's ability to meet the requirements for registered organizations set forth under PHL §§ 3364 and 3365, and 10 NYCRR §§ 1004.5 and 1004.6.

The hearing will be held in accordance with PHL § 3393, 10 NYCRR Part 51, Article 3 of the State Administrative Procedure Act ("SAPA") and any other applicable laws and regulations deemed relevant by the Administrative Law Judge. A stenographic record of all proceedings will be made and witnesses will be sworn and examined. Each Petitioner may appear in person or by an attorney, testify, present documentary evidence, produce witnesses, cross-examine adverse witnesses, examine such evidence as may be produced and request the issuance of subpoenas. The Petitioners have the burden of proof and the burden of going forward in this matter, pursuant to SAPA § 306 and 10 NYCRR § 51.11(d)(6).

The hearing shall be limited to the issues of whether, for each Petitioner, the application for registration as a registered organization demonstrates that: (1) the Petitioner

meets the requirements for registered organizations set forth in PHL §§ 3364 and 3365, and 10 NYCRR §§ 1004.5 and 1004.6; and (2) the Petitioner is one of the five most qualified organizations that submitted applications on or before June 5, 2015 for registration as a registered organization, based on the Petitioner's ability to meet the requirements for registered organizations set forth under PHL §§ 3364 and 3365, and 10 NYCRR §§ 1004.5 and 1004.6.

If a Petitioner does not appear at the hearing, either in person or by an attorney, the aforementioned issues, with regard to that particular Petitioner, will be decided in the Department's favor and the Department's decision to not select the Petitioner for registration as one of the five registered organizations will be upheld. At the conclusion of the hearing, the Administrative Law Judge will prepare a report, including findings of fact, conclusions, and recommendations, based on evidence presented at the hearing. After receipt of the report of the Administrative Law Judge, the Commissioner will make a final determination whether the Department's decisions to not approve each of the Petitioner's applications for registration as one of the five registered organizations under PHL §§ 3364 and 3365, and 10 NYCRR § 1004.6(b), should be upheld.

Pursuant to § 301(6) of the State Administrative Procedure Act, if any party or witness to this proceeding is a deaf person, the Department, upon reasonable notice, will provide at no charge a qualified interpreter of the deaf to interpret the proceedings to and the testimony of any deaf person.

Any request for adjournment of the hearing must be made in writing to the Supervising Administrative Law Judge, Bureau of Adjudication, New York State Department of Health, Riverview Center, 150 Broadway, Suite 510, Albany, New York 12204. Notice of

any adjournment request must also be provided to the Department's assigned attorney whose name and telephone number appear below. SCHEDULED HEARING DATES ARE CONSIDERED DATES CERTAIN AND WILL NOT BE ADJOURNED WITHOUT A COMPELLING REASON.

DATED: Albany, New York
October 11, 2017

Howard A. Zucker, M.D., J.D.
Commissioner of Health

BY: 
Richard J. Zahnleuter
General Counsel
Division of Legal Affairs
Tower Building, Room 2438
Empire State Plaza
Albany, NY 12234
(518) 474-7553
richard.zahnleuter@health.ny.gov

Inquiries to: Mark Fleischer
Assistant Counsel
Telephone No.: (518) 473-1707
Fax No.: (518) 486-1858
Email: mark.fleischer@health.ny.gov

Appendix

Advanced Grow Labs New York, LLC

Alternative Medicine Associates, LLC

Brightwaters Farms LLC

Butler Evergreen, LLC

CCCONY, Inc. (Compassionate Care Centers of NY, Inc.)

Far(m)ed New York, LLC

Good Green Group LLC

Herbal Agriculture LLC

Hudson Health Extracts, LLC

LabCare, Inc.

Medigro Organics LLC

New York Medical Growers, LLC

North Country Roots, Inc.

THC Health Inc.

Tilray New York, LLC

EXHIBIT F

STATE OF NEW YORK : DEPARTMENT OF HEALTH

-----X

IN THE MATTER OF

OF

ORDER SUA SPONTE
SEVERING
PETITIONERS' CLAIMS

UNSELECTED APPLICATIONS FOR REGISTRATION
AS REGISTERED ORGANIZATIONS TO MANUFACTURE
AND DISPENSE MEDICAL MARIHUANA UNDER
NEW YORK'S COMPASSIONATE CARE ACT BY THE
ORGANIZATIONS IDENTIFIED IN APPENDIX A

Petitioners,

pursuant to Article 33 of the Public Health Law of the State
of New York and Part 1004 (Chapter XIII, Title 10 (Health)
of the Official Compilation of Codes, Rules and
Regulations of the State of New York (NYCRR).

-----X

The Department served a Notice of Hearing upon fifteen Petitioners that had requested a hearing because they had not been selected as registered organizations to manufacture and dispense medical marihuana under the Compassionate Care Act. Eight Petitioners either withdrew or failed to appear at the hearing on January 10, 2018. Therefore, the number of Petitioners in this proceeding was reduced from fifteen to seven. Five additional hearing days have been held on February 26, March 26, April 25, June 5 and June 6, 2018. At my request, the Department presented evidence to establish the process used by the Department to evaluate the applications for registration by presenting the testimony of three witnesses and obtaining the admission of documents into evidence. The seven Petitioners have each had an opportunity to cross examine the witnesses called by the Department.

Although some economy may have been gained by beginning the record in these requested hearings in a consolidated manner with a presentation by the Department of testimony and documents establishing the methodology used in selecting applications for registration, scheduling

further joint hearing dates for the seven Petitioners may cause inconvenience and prejudice. Instead, I will separately schedule and hear the seven Petitioners' claims in order to further the prompt and efficient disposition of these matter.

IT IS HEREBY ORDERED:

Pursuant to 10 NYCRR § 51.11(b)(2), the claims of the seven Petitioners are SEVERED.

Dated: Menands, New York
September 11, 2018



WILLIAM J. LYNCH
Administrative Law Judge

Appendix A

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EXHIBIT G

Registered Organization Evaluation Tool

Sub Categories	Applicant Total Points:	Point Factor	Applicant Final Score	Percentage
Miscellaneous	7.50	0.33	2.50	2
Product Manufacturing	69.50	0.40	27.92	22.3392857
Security	63.00	0.07	4.34	3.47586207
Transportation & Distribution	15.50	0.19	2.95	2.36190476
Sales & Dispensing	27.50	0.16	4.28	3.42222222
Quality Assurance & Staffing	93.00	0.17	15.92	12.7351351
Real Property and Equipment	12.00	0.56	6.67	5.33333333
Geographic Distribution	4.00	3.00	12.00	9.6
Architectural Design Avg.	68.34	0.02	1.59	1.27099849
Financial Standing	2.00	4.00	8.00	6.4
Organizational Structure	Pass/Pass			
TOTAL POINTS	362.34		86.17	68.9387417

Registered Organization Evaluation Tool

Item	Evaluation Process	Evaluator	Score (Pass or Fail)	Comments
1	Receipt of application by due date and time.	MMP Staff	Pass	
2	Non-refundable \$10,000 application fee and refundable \$200,000 registration fee in the form of a certified check are enclosed.	MMP Staff	Pass	
3	All required attachments as outlined in section I are included (section I, attachments A through M).	MMP Staff	Pass	
4	The applicant's CEO duly authorized by the board, or general partner or owner has signed the application.	MMP Staff	Pass	
5	Appendix A and Appendix B have been submitted	MMP Staff	Pass	

EVALUTION RATINGS: EXPLANATION & DEFINITIONS

For each review item, the following standard rating system must be used by evaluators to evaluate the applicant's submitted information pertaining to that item, unless another scale is provided.

Points	Rating	Rating Description
3	Excellent	The applicant met or exceeded the minimum criteria for the item being evaluated by clearly demonstrating a better than average level of performance.
2	Average	The applicant met the minimum criteria expected for the item being evaluated. The applicant clearly demonstrated an adequate level of performance.
1	Fair	The applicant met the minimum criteria expected for the item being evaluated. However, based on the information provided the applicant failed to clearly demonstrate an adequate level of performance.
0	Poor	The applicant did not meet the minimum criteria for the item being evaluated. The applicant was not responsive to the item being evaluated. If the criteria receiving a zero is specific to the application requirement in 1004.5 and the applicant fails to provide the information or the criteria receiving a zero is on the Geographic Distribution scoring, then the Department will send a notice pursuant to 1004.6(d) prior to awarding registrations. These sections are highlighted in orange throughout the evaluation tool.

Item	Consideration Criteria	Evaluation Process	Evaluator	Final Score
1	Attachment A & Attachment C	The applicant demonstrates that he or she possesses or has the right to use sufficient real property, buildings and equipment to properly carry on the activity described in its operating plan.	HPA	7

	Final Score
The applicant identifies all real property, buildings, and facilities to be used in manufacturing and dispensing	3
The applicant provided copies of all applicable executed and proposed deeds, leases, and rental agreements or executed option contracts showing right to use sufficient land, buildings, other premises, and equipment identified, or proof of \$2,000,000 bond provided.	2
All submitted lease agreements contain required language from §1004.5 (b) (9)	2
	7

Item	Consideration Criteria	Evaluation Process	Evaluator	Final Score
2	Attachment B	The applicant identified all equipment that will be used to carry out the manufacturing, processing, transportation, distributing, sale and dispensing activities described in the application and operating plan, pursuant to PHL § 3365 and 10 NYCRR § 1004.5(b)(3).	Wadsworth* PRS SHP	5

	Wadsworth Score	PRS Score	SHP Score	Average Score
The applicant has identified all equipment to be used in the following: (provided as in Attachment D)				
Manufacturing & Processing*	2			2
Transportation & Distribution		1	1	1
Sale & Dispensing		2	2	2
	2	3	3	5

Item	Consideration Criteria	Evaluation Process	Evaluator	HSS 3 Score	HSS 1 Score	Average Score
1	Attachment D - Section 2	The applicant's submitted operating plan for transporting and distribution policies and procedures clearly demonstrates compliance with Article 33 and Title 10 Part 1004.	HSS 3 HSS 1	16	15	15.5

	HSS 3 Score	HSS 1 Score	Average Score
The applicant demonstrates that delivery times must be randomized.	3	3	3
The applicant's staffing plan includes a minimum of two employees staff all transport vehicles.	2	2	2
The applicant demonstrates that one employee shall stay with the transport vehicle at all times.	3	2	2.5
The applicant demonstrates that the transport team shall possess copy of the shipping manifest at all times.	2	2	2
The applicant demonstrates that the shipping manifest shall be completed prior to transport.	2	2	2
The applicant demonstrates that a copy of shipping manifest shall be transmitted to the dispensing facility and the Department 2 days prior to transport.	2	2	2
The applicant demonstrates that shipping manifests shall be maintained for a period of 5 years.	2	2	2
	16	15	15.5

Item	Consideration Criteria	Evaluation Process	Evaluator	HSS 3 Score	HSS 1 Score	Average Score
1	Attachment D - Section 5 Attachment H	The applicant's operating plan demonstrates the ability to meet the security requirements outlined in 1004.13 for manufacturing and dispensing facilities.	HSS 3 HSS 1	25	21	23

	HSS 3 Score	HSS 1 Score	Average Score
Utilize Only Commercial Grade Equipment	2	2	2
Motion Detectors	3	3	3
Video Cameras and Recordings	2	2	2
Alarms:			
Perimeter Alarm	2	2	2
Duress Alarm	3	2	2.5
Panic Alarm	3	2	2.5
Holdup Alarm	3	2	2.5
Back Up Alarm	2	2	2
Automatic Voice Dialer	3	2	2.5
Failure Notification System	2	2	2
	25	21	23

Item	Consideration Criteria	Evaluation Process	Evaluator	HSS 3 Score	HSS 1 Score	Average Score
2	Attachment D - Section 5 Attachment H	The applicant's operating plan demonstrates the ability to meet the security requirements outlined in 1004.13 for the transport of marijuana from manufacturing facilities to dispensing facilities.	HSS 3 HSS 1	11	12	11.5

	HSS 3 Score	HSS 1 Score	Average Score
The applicant demonstrates that marijuana product will be transported in a locked safe or secure storage compartment that is part of the transporting vehicle	3	3	3
The applicant demonstrates that the storage compartment will not be visible from outside the vehicle	2	2	2
The applicant demonstrates that employees will travel directly from manufacturing to dispensing facility with no unnecessary stops.	2	3	2.5
The applicant demonstrates that transport team members will have access to a secure form of communication with employees of the manufacturing facility at all times	2	2	2
The applicant demonstrates that the transport team will possess copy of the shipping manifest at all times.	2	2	2
	11	12	11.5

Item	Consideration Criteria	Evaluation Process	Evaluator	HSS 3 Score	HSS 1 Score	Average Score
3	Attachment D - Section 5 Attachment H	The applicant's operating plan demonstrated policies and procedures related to security and control measures that will be in place to prevent diversion, abuse and other illegal or unauthorized conduct relating to medical marijuana.	HSS 3 HSS 1	30	27	28.5

	HSS 3 Score	HSS 1 Score	Average Score
The applicant demonstrates that all security system equipment and recordings will be maintained in a secure area to prevent loss, theft destruction or alteration.	2	2	2
The applicant demonstrates that access will be limited to persons essential to surveillance operations, law enforcement, security system employees and the Department.	2	1	1.5
The applicant will maintain a current list of authorized employees and service employees having access to any surveillance room will be maintained.	2	2	2
The applicant demonstrates that the onsite surveillance room will remain locked.	2	1	1.5

The applicant demonstrates that the onsite surveillance rooms will not be used for any other function.	1	0	0.5
The applicant demonstrates that the outside perimeter of facility will be illuminated.	2	1	1.5
The applicant demonstrates that the facility will be kept securely locked and protected from unauthorized entry at all times.	3	3	3
The applicant demonstrates that marijuana not part of a finished product will be stored in a secure location accessible to minimal essential employees essential for efficient operation.	2	2	2
The applicant demonstrates that medical marijuana products, approved or ready for testing will be stored in a department approved safe or vault.	2	2	2
The applicant demonstrates that approved safes, vaults or other equipment or areas for storage will be securely locked except for the time required to replace or remove.	2	2	2
The applicant demonstrates that keys will not be left in locks.	2	2	2
The applicant demonstrates that security measures (combination numbers, passwords or biometric security systems etc.) will only be accessible to authorized employees.	2	2	2
Security system has the ability to remain operational during a power outage.	2	2	2
The applicant demonstrates a plan for equipment testing (no less than monthly) at each manufacturing facility and dispensing facility.	2	3	2.5
The applicants' detailed floor plans indicate activities performed in each area.	2	2	2
	30	27	28.5

Item	Consideration Criteria	Evaluation Process	Evaluator	HSS1	HSS3	Average Score
1	Attachment F	The applicant has entered into a labor peace agreement with a bona-fide labor organization, as defined in section 3360 of the PHL, that is actively engaged in representing or attempting to represent the applicant's employees.	MMP Staff	2	2	2

Item	Consideration Criteria	Evaluation Process	Evaluator	SHP	PRS	Average Score
2	Attachment M	The applicant submitted a statement demonstrating that it is able to comply with all applicable state and local laws and regulations relating to the activities in which it intends to engage under the registration.	MMP Staff	2	3	2.5

Item	Consideration Criteria	Evaluation Process	Evaluator	HPA	Average Score
3	Attachment L	The applicant submitted a timeline demonstrating the estimated timeframe from growing marijuana to production of a final approved product.	MMP Staff	2	2

Item	Consideration Criteria	Evaluation Process	Evaluator	MMP Staff	Average Score
4	Application Appendix A Appendix B All supporting attachments	The applicant demonstrates that it is in the public's interest that the registration be granted.	MMP Staff	1	1

Consideration Criteria	Evaluation Criteria	Evaluator	Pass/Fail
Appendix A	The applicant's organizational structure demonstrated moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization.	MMP Staff	Pass
Attachment E	The applicant has attached copies of the organizational and operational documents of the applicant, pursuant 10 NYCRR § 1004.5(b)(5), which includes the identification of all those holding an interest or ownership in the applicant and the percentage of interest or ownership held.	MMP Staff	Pass

Evaluator: Wadsworth

Items highlighted in Orange that score a zero will be subject to a notification detailed in 1004.6 (d)

Item	Consideration Criteria	Wadsworth score 1	Wadsworth Score 2	Average Score
A description of each proposed brand (up to a total of five), the form it will be produced in, the total THC and the total CBD content and all inactive ingredients used to produce each MMP				
	One brand must have high CBD and low THC	1	1	1
	One brand must have ~ equal amounts of CBD and THC	1	1	1
	Maximum of 10mg THC per dose	1	1	1
	Excipients must be pharmaceutical grade	0	0	0
	Must be an approved form	2	2	2
	No synthetic marijuana additives are used	1	1	1
A standard operating procedure manual that includes a detailed description of the applicant’s manufacturing facility and processes (manufacturing is defined in 1004.11 as follows: “Manufacturing” shall include, but not be limited to cultivation, harvesting, extraction (or other processing), packaging and labeling), inventory management and documentation of all phases of the production process and products.				
	Manufacturing must occur indoors (may include a greenhouse for growing).	1	1	1
	Demonstrates that production of any approved medical marihuana product shall be in accordance with general sanitary conditions. Poisonous or toxic materials, including but not limited to insecticides, rodenticides, detergents, sanitizers, caustics, acids and related cleaning compounds must be stored in a separate area from the marihuana and medical marihuana products in prominently and distinctly labeled containers, except that nothing herein precludes the convenient availability of detergents or sanitizers to areas where equipment, containers and utensils are washed and sanitized	2	2	2
	Addresses in adequate detail all methods for cultivation (seeds and propagation material, soil and fertilization, irrigation, lighting, humidity/moisture, temperature, ventilation, diseases and pests control, use of plant growth regulators, etc.)	8	4	6

harvesting (harvest timing, post-harvest handling)	4	2	3
extraction (protocols, procedures, equipment)	8	4	6
Extractions must be by CO2 or alcohol extraction (of the appropriate quality) only	1	1	1
Extraction is performed only with the leaves and flowers of female marijuana plants	1	0	0.5
Addresses packaging/labeling/sealing (protocols, label content)	8	8	8
Labeling and packaging must be as specified in regulations*			
(k) Each approved medical marihuana product shall be affixed with a product label. Medical marihuana product labels shall be approved by the department prior to use. Each product label shall be applied at the manufacturing facility, be easily readable, firmly affixed and include:			
(1) the name, address and registration number of the registered organization;			
(2) the medical marihuana product form and brand designation;			
(3) the single dose THC and CBD content for the product set forth in milligrams (mg);			
(4) the medical marihuana product lot unique identifier (lot number or bar code);			
(5) the quantity included in the package;			
(6) the date packaged;			
(7) the date of expiration of the product;			
(8) the proper storage conditions;			
(9) language stating:			
(i) "Medical marihuana products must be kept in the original container in which they were dispensed and removed from the original container only when ready for use by the certified patient";			
(ii) "Keep secured at all times";			

(iii) "May not be resold or transferred to another person";			
(iv) "This product might impair the ability to drive";			
(v) "KEEP THIS PRODUCT AWAY FROM CHILDREN (unless medical marihuana product is being given to the child under a practitioner's care)"; and			
(vi) "This product is for medicinal use only. Women should not consume during pregnancy or while breastfeeding except on the advice of the certifying practitioner, and in the case of breastfeeding mothers, including the infant's pediatrician."			
Addresses storage (unusable marijuana, medical marijuana products prior to passing QC testing, long-term storage of lots and retained samples, quarantined, returned or out of specification product)	2	4	3
Includes a description of how all methods for manufacturing conform to Good Agricultural Practices	4	4	4
Includes validated standard operating procedures to demonstrate that the applicant will be able to produce and dispense consistent and reproducible medical marihuana product such that, for each form of each brand produced, there is homogeneity, absence of contamination and reproducibility of the brand profile in each lot as defined in section 1004.11 of this part.	4	8	6
Has a plan for or has previously completed stability studies, to demonstrate the stability of the opened (minimum of 60 days) and of unopened MMPs	2	2	2
Includes a description of the source and quality of water used in manufacturing of the MMP	1	1	1
Includes a policy describing the use, or non-use, of pesticides, fungicides and herbicides	0	2	1
Includes a description of how the RO will track (must have unique identifier), document, investigate and perform corrective action for any contamination incident.	8	8	8

	Includes a plan for visual examination of marijuana for mold, mildew pests, rot or gray or black plant material is required).	1	1	1
	Must address storage of any contaminated materials to be destroyed.	1	1	1
A description of the quantity of each brand to be produced and the time frame with key benchmarks for production of each proposed MMP brand over the next year. Each registered organization shall demonstrate the availability of at least a one year supply of any offered brand unless otherwise allowed by the department.		4	4	4
		2	2	2
A description of procedures and policies for laboratory testing including a description of the analysis performed to determine the appropriate number of MMP samples to be tested for each brand lot at an appropriate laboratory and the method for selecting such samples from each lot of MMP produced.	At a minimum those microbes/analytes required by the regulations are tested	1	0	0.5
	Testing is performed on sealed MMPs sent to the laboratory via secure method with COC intact	0	1	0.5
A description of procedures and policies for retention (and storage conditions) of an adequate number of each lot of final MMPs (as would be provided to the patient) for future testing.	The quantity retained shall be described and shall be a statistically representative number of samples to allow for complete testing of the product at least three times and shall be retained by the registered organization for at least two years following the date of expiration.	2	2	2
		71	68	69.5

Evaluators: Wadsworth

Items highlighted in Orange that score a zero will be subject to a notification detailed in 1004.6 (d)

Item	Consideration Criteria	Wadsworth Score 1	Wadsworth Score 2	Average Score
A description of record maintenance (5 years). Records for personnel training and competence monitoring, cultivation, extraction, packaging, labeling and laboratory testing		0	0	0
A description of how the lot numbers of all components used in the manufacture of MMPs will be tracked		4	4	4
A staffing plan including an org chart and a description of the roles of all employees (Attachment J)				
	all staff must be over 21 years of age	4	4	4
	includes FTEs, responsibilities and relationships of individuals within the organization are clearly indicated	1	1	1
	Indicates who has access to marijuana, extracts or medical marijuana products	4	4	4
	Must include a description of background checks to verify no one coming into contact with medical marijuana has any disqualifying convictions	0	0	0
	Includes a description of the employee training program for general sanitary practices)	4	0	2
	Must include a description of the experience of at least one employee with GAP experience (a minimum of 1 year is required)	16	16	16
	Must include a description of the training and experience of one employee who will act as the QA officer and how the latter will oversee the QA program	16	16	16
	Must include NYS licensed pharmacists for dispensing facilities	1	1	1
Includes a description of how the RO will prevent contamination of the MMP and how it will monitor and test for such contaminants		16	16	16
Includes a description of how the RO will document and investigate returns, complaints and adverse events, and its process to provide for rapid voluntary or involuntary recalls of any lot of medical marihuana product		16	16	16
Must include a requirement that adverse events and total recalls are reported to the department within twenty-four hours of their occurrence		8	8	8

Must include a policy for retesting of returned approved medical marihuana products		0	0	0
A description of methods to quarantine any lot of medical marihuana product as directed by the department or if initiated internally		4	4	4
A description of methods to dispose of unusable medical marihuana products that have failed laboratory testing or any unsuitable marihuana or medical marijuana products generated in the manufacturing process or recalled		1	1	1
		95	91	93

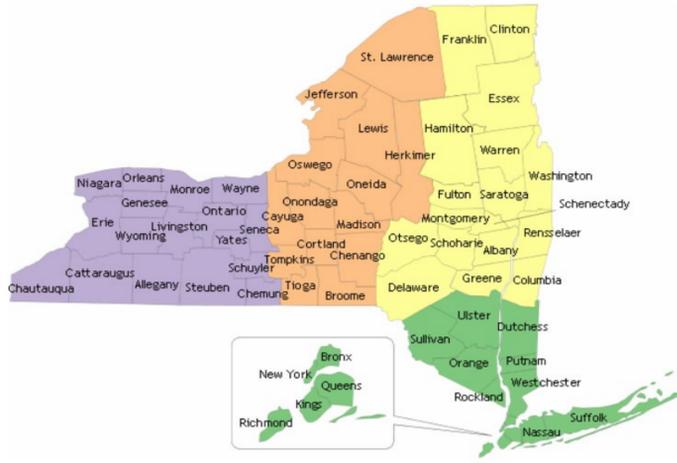
Consideration Criteria	Evaluation Process	Evaluator	Score (Pass/Fail)
Attachment K	The applicant submitted proof that all of the applicant's proposed manufacturing and dispensing facilities have, or will have, internet connectivity.	MMP Staff	Pass

Item	Consideration Criteria	Evaluation Process	Evaluator	Nicole Score	Pharmacist Score	Weighted Average Score
1	Attachment D - Section 3	The applicant's submitted operating plan for sales and dispensing policies and procedures demonstrates compliance with Article 33 and Title 10 Part 1004.	Nicole Pharmacist	28	21	24.5

		Nicole Score	Pharmacist Score	Total Score
Policies and procedures demonstrate operation with a pharmacist supervision of activity at the dispensing facility at all times during business hours.		2	0	1
Policies and procedures demonstrate dispensing of only approved medical marijuana products.		2	0	1
Policies and procedures demonstrate dispensing of approved medical marijuana products only to certified patients or their designated caregivers.		2	1	1.5
Dispensing policies and procedures demonstrate that the dispensing facility will not dispense an amount greater than a thirty (30) day supply to a certified patient, and not until the patient has exhausted all but a seven day supply provided pursuant to any previously dispensed medical marijuana product by any registered organization.		2	2	2
Dispensing policies and procedures demonstrate that packaging shall remain unopened by dispensing facility staff.		2	2	2
Dispensing policies and procedures demonstrate maintenance of a patient specific log of medical marijuana products that can be provided to the patient, patient's designated caregiver, or the patient's practitioner.		2	2	2
Dispensing facility policies and procedures demonstrate how access to the dispensing facility will be limited to certified patients and designated caregivers.		2	2	2
Dispensing facility policies and procedures demonstrate how visitors will be managed.		2	2	2
Dispensing facility policies and procedures demonstrate that dispensing labels will include the elements defined in 1004.12 (k).		2	0	1
	(h) the dispensing facility shall affix to the approved medical marijuana product package a patient specific dispensing label approved by the department, that is easily readable, and firmly affixed and includes:			
	(1) the name and registry identification number of the certified patient and designated caregiver, if any;			
	(2) the certifying practitioner's name;			
	(3) the dispensing facility name, address and phone number;			
	(4) the dosing and administration instructions;			
	(5) the quantity and date dispensed; and			
	(6) any recommendation or limitation by the practitioner as to the use of medical marijuana.			
Dispensing facility policies and procedures demonstrate how products will be stored at the dispensing facility to ensure that there is no contamination or deterioration.		2	2	2
The registered organization's operating plan includes disposal policies and procedures for products that are at the dispensing facility, but cannot be dispensed.		4	4	4
The registered organization's operating plan includes policies and procedures for documenting and monitoring patient complaints.		4	4	4
		28	21	24.5

Item	Consideration Criteria	Evaluation Process	Evaluator	WW score 1	WW Score 2	Average Score
2	Attachment D - Section 4	The applicant provided a detailed description of any devices used with approved medical marijuana products to be offered or sold by the registered organization.	Wadsworth*	3	3	3

4	Hazardous Materials Control Areas	0	0	0	0	0
5	Building Area & Height	0	0	0	0	0
6	Incidental Use Areas	0	0	0	0	0
7	Mixed Occupancies	0	0	0	0	0
8	Nonseparated Uses	0	0	0	0	0
9	Separated Uses (Ratio < 1)	0	0	0	0	0
10	Construction Classification	2	0	0	0	0
11	Fire Resistance Rating Req'm't for Building Elements	0	0	0	0	0
12	Exterior Wall Fire-Resistance Rating	0	0	0	0	0
13	Exterior Fire Separation Distance	0	0	0	0	0
14	Fire Walls	0	0	0	0	0
15	Fire Barriers	0	0	0	0	0
16	Shaft Enclosures	0	0	0	0	0
17	Fire Partitions	0	0	0	0	0
18	Horizontal Assemblies	0	0	0	0	0
19	Fire Protection: Sprinkler System	1	0	0	0	0
20	Alt. Fire Extinguishing System	0	0	0	0	0
21	Standpipe System	0	0	0	0	0
22	Fire Alarm & Detection Systems	1	0	0	0	0
23	Emergency Alarm System	0	0	0	0	0
24	Fire Department Connections	2	0	0	0	0
25	Exits	2	0	0	0	0
26	Occupant Load	1	0	0	0	0
27	Egress Width	1	0	0	0	0
28	Accessible Means of Egress	0	0	0	0	0
29	Doors, Gates, and Turnstiles	0	0	0	0	0
30	Interior Stairs	2	0	0	0	0
31	Ramps	0	0	0	0	0
32	Common Path of Travel	1	0	0	0	0
33	Exit Doorway Arrangement	1	0	0	0	0
34	Corridor Fire Rating	2	0	0	0	0
35	Corridor Width	2	0	0	0	0
36	Dead End Corridor	2	0	0	0	0
37	Number of Exits and Continuity	2	0	0	0	0
38	Vertical Exit Enclosures	2	0	0	0	0
39	Exit Passageways	2	0	0	0	0
40	Horizontal Exits	2	0	0	0	0
41	Exterior Exit Ramps & Stairways	2	0	0	0	0
42	Exit Discharge	2	0	0	0	0
43	Accessibility	1	0	0	0	0
44	Energy Conservation	2	0	0	0	0
45	Emergency & Standby Power	2	0	0	0	0
46	Smoke Control Systems	2	0	0	0	0
47	Plumbing Fixture Count	0	0	0	0	0
48	Available Street Water Pressure	2	0	0	0	0
49	Fire Apparatus Access Road	2	0	0	0	0
		47	0	0	0	0



Evaluators: MMP Staff (PRS3 and SHP)

A score of zero will be subject to a notification detailed in 1004.6 (d)

1. List the applicant under applicant name.
2. Add the county name where the applicant proposes to locate the dispensing facility.
Neighboring also includes counties divided by a body of water.

Point Assignment for scored spreadsheet:

- 4 Points = All 4 dispensing facilities are in non-neighboring counties.
- 3 Points = At least 2 of the 4 dispensing facilities are in non-neighboring counties. No more than 1 dispensing facility in a county.
- 2 Points = All 4 facilities are in neighboring counties, with no duplicates in any one county.
- 1 Point = Multiple dispensing facilities in same county, but not all 4 in the same county.
- 0 Points = All 4 dispensing facilities are not provided or all 4 dispensing facilities are in the same county.

Please refer to the example provided in the first line below.

Applicant Name	Facility 1	Facility 2	Facility 3	Facility 4	PRS3 Score	SHP Score	Average Score
<i>John Doe</i>	<i>Suffolk</i>	<i>Albany</i>	<i>Oswego</i>	<i>Erie</i>			
Hudson Health Extracts LLC	Albany	Bronx	Suffolk	Erie	4	4	4

Consideration Criteria	Evaluation Process	Evaluator	Score (Pass/Fail)
Attachment G	The applicant has attached a financial statement setting forth all elements and details of any business transactions connected with the application, including but not limited to all agreements and contracts for consultation and/or arranging for the assistance in preparing the application, pursuant to 10 NYCRR § 1004.5(b)(10).	DOH Audit Services Unit	Pass
Attachment I	The applicant has attached the most recent financial statement of the applicant prepared in accordance with generally accepted accounting principles (GAAP) applied on a consistent basis and certified by an independent certified public accountant, in accordance with the requirements of 10 NYCRR § 1004.5(b)(16).	DOH Audit Services Unit	Pass

Item	Consideration Criteria	Evaluation Process	Evaluator	Score
1	Independent Financial Consultant Review	Independent Financial Consultant will review Attachment I and Attachment G to determine financial standing of the applicant.	DOH Audit Services Unit	2

EXHIBIT H



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

December 29, 2017

Petitioners Identified
& Addresses Indicated
in Appendix A

Mark Fleischer, Esq.
NYS Department of Health
Corning Tower Room 2412
Empire State Plaza
Albany, NY 12237

Re: In the Matter of Unselected Applications for Registration
As Registered Organizations to Manufacture and Dispense
Medical Marihuana Under New York's Compassionate
Care Act by Organizations Identified in Appendix A

Dear Petitioners and Mr. Fleischer:

The hearing in this matter is scheduled to commence on January 10, 2018. I am writing to provide you with further information regarding the manner in which this hearing will be conducted. The Department had indicated that it would be providing voluminous exhibits which include excel spreadsheets that summarize and set forth detailed breakdowns of the scores received by each of the 44 applicants. The first hearing day will be limited to the Department's opening statement, offer of documents into evidence, and presentation of testimony regarding the process used to evaluate the applications for registration. The Petitioners will have an opportunity to cross examine any witness called by the Department.

Due to the number of Petitioners, I expect that several additional hearing days may be required, and I will schedule those additional days at the conclusion of the first hearing day. As stated in the Notice of Hearing, if a Petitioner does not appear at the hearing, either in person or by an attorney, the Department's decision with regard to that particular Petitioner will be upheld. As of now, three Petitioners have decided to withdraw from this proceeding. If any additional entities wish to withdraw as a Petitioner in this proceeding, please complete and return the enclosed form to my attention at the address below or by fax to 518-402-0751.

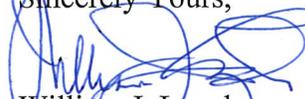
I previously sent you a letter addressing several issues raised in Mr. Fleischer's November 2, 2017 letter. Rather than respond to the question related to the scope of the issue to be determined by this proceeding, I invited the parties to send me a letter stating their position. The responses from Petitioners included the following:

- The review should not be limited to whether a Petitioner is one of the five most qualified applicants. Instead, consideration should be expanded to whether a Petitioner can demonstrate that it should have scored higher than any of the ten applicants that were actually issued registrations by the Department.
- The review should include whether the Department failed to follow the statutorily prescribed procedure mandated by PHL § 3365(3)(b) and 10 NYCRR § 1004.6(d), which provides that “If the commissioner is not satisfied that the applicant should be issued a registration, he or she shall notify the applicant in writing of those factors upon which further evidence is required.”
- The scope of the review should be to determine whether the Department’s scoring methodology was consistent with PHL §§ 3360-3369-e, and its implementing regulations, and whether the scoring methodology was properly applied. If a Petitioner can demonstrate that its application should have received an equivalent or higher score than an applicant that is now registered, the Petitioner’s application should be approved with no impact on any other entity.

Having considered the parties’ submissions, the scope of the hearing will be limited to whether the Department’s scoring methodology for the applicants for registration as registered organizations to manufacture and dispense medical marihuana under New York’s Compassionate Care Act was consistent with PHL §§ 3360-3369-e and 10 NYCRR Part 1004, and whether the scoring methodology was properly applied.

As pointed out by one of the Petitioners, PHL § 3365(3)(b) and 10 NYCRR § 1004.6(d), state that the Commissioner is required to notify an applicant in writing of the factors upon which further evidence is required if the Commissioner is not satisfied that the applicant should be issued a registration. However, PHL § 3365(9) states both that “the commissioner shall register no more than five registered organizations,” and that “the commission [sic] may register additional registered organizations. This creates the possibility that the Commissioner was satisfied that that an applicant should be issued a registration, but limited the selection to the highest scoring applicants who satisfied the evidentiary requirements. I request that the Department address this issue on the record at the first hearing day.

Sincerely Yours,



William J. Lynch
New York State Department of Health
Bureau of Adjudication
Riverview Center
150 Broadway - Suite 510
Menands, New York 12204

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David Lipton, Managing Partner
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West Haven, CT 06516

Alternative Medicine Associates LLC
Dr. Gregory Daniel, Chief Executive Officer
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Herbal Agriculture LLC
Gary Smith, Chief Executive Officer
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Hudson Health Extracts LLC*
Mr. Mitch Baruchowitz, Managing Member
29 Beck Avenue
Rye, NY 10508

Labcare Inc.
Daniel J. Casacci, President
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No attorney

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No attorney

New York Medical Growers LLC
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THC Health, Inc.*
Christian Cespedes, President/ CEO
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Tilray New York LLC*
Luke Wilson, General Manager
1920 East Lake Avenue E
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Mark Fleischer, Esq.
NYS Department of Health
Corning Tower Room 2412
Empire State Plaza
Albany, NY 12237
mark.fleischer@health.ny.gov

* I have received no reply from these Petitioners.

STATE OF NEW YORK : DEPARTMENT OF HEALTH

-----X

IN THE MATTER :

OF :

UNSELECTED APPLICATIONS FOR REGISTRATION AS :
REGISTERED ORGANIZATIONS TO MANUFACTURE AND :
DISPENSE MEDICAL MARIHUANA UNDER NEW YORK'S :
COMPASSIONATE CARE ACT BY THE ORGANIZATIONS :
IDENTIFIED IN APPENDIX A, :

WITHDRAWAL

AND

Petitioners, :

WAIVER

pursuant to Article 33 of the Public Health Law of the State of :
New York and Part 1004 (Chapter XIII, Title 10 (Health) of the :
Official Compilation of Codes, Rules and Regulations of the :
State of New York. :

-----X

_____ hereby withdraws as a Petitioner in this proceeding
and waives any right to a hearing in this matter.

DATED: _____

SIGNATURE

PRINTED NAME

PRINTED TITLE

EXHIBIT J



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

August 28, 2018

Petitioners Identified
& Addresses Indicated
in Appendix A

Mark Fleischer, Esq.
NYS Department of Health
Corning Tower Room 2412
Empire State Plaza
Albany, NY 12237

Re: In the Matter of Unselected Applications for Registration
As Registered Organizations to Manufacture and Dispense
Medical Marijuana Under New York's Compassionate
Care Act by Organizations Identified in Appendix A

Dear Petitioners and Mr. Fleischer:

I am writing in response to the following submissions and in regard to the scheduling of further proceedings in this matter. Upon consideration of the pertinent regulations and the scope of this administrative hearing, I see no basis upon which to issue the requested subpoenas because they would elicit cumulative, privileged or irrelevant material.

Daniel Casacci submitted an email on July 8, 2018, on behalf of LabCare, Inc., requesting that I issue a subpoena for the person who graded the financial section of its application.

Michael Korsinsky submitted a letter dated July 9, 2018, on behalf of New York Medical Growers, LLC ("NYMG"); Compassionate Care Center of New York ("CCCoNY"); and Hudson Health Extracts ("HHE"), requesting that I issue subpoenas to require the testimony of 15 additional current or former Department employees and to require the production of several documents including hard copies of the individual score sheets, all versions of application evaluation records, copies of the evaluators' conflict of interest statements, copies of all documentation with Registered Organization ("RO") applicants after the submission deadline, copies of attendance lists for all staff training, employee records for any person no longer with the Department who was involved in the grading and evaluation process, copies of all emails and correspondence related to the conversion factors, modified unredacted copies of the applications of the 10 current ROs, copies of all communications with RO applicants after the submission deadline, copies of all Department requests for information and responses, names of the principal stakeholders and dates of executed leases for a current RO, as well as copies of several documents related to communications after the submission deadline between the Department and the 10 current ROs.

Stephen Steeneck submitted a letter dated July 9, 2018, on behalf of Good Green Group, LLC, requesting that I issue subpoenas for the person in charge of handling Freedom of Information Law (“FOIL”) requests or the FOIL Administrator, the person responsible for deciding which documents should be placed on the Department’s website, and the person responsible for placing the RO applications on the Department’s website.

Mark Fleischer submitted a responding letter dated August 10, 2018, on the Department’s behalf. He states that the requests contained in Mr. Korsinsky’s letter are indistinguishable from pre-trial discovery, and he notes that the purpose may also be to discover information for a legal action filed in Supreme Court Nassau County by Petitioners NYMG, CCCofNY and HHE. His letter addresses in detail the Department’s objection to each of the requested witnesses and documents.

Mr. Korsinsky submitted an email on August 21, 2018, claiming that Mr. Fleischer’s response referencing the Supreme Court action went beyond the scope of this hearing and that the Supreme Court action does not interfere with this proceeding.

As stated in my prior letter dated May 8, 2018, SAPA § 305 granted the Health Department the authority to adopt rules providing for discovery and depositions to the extent and in the manner appropriate to its proceedings, and the Health Department has adopted 10 NYCRR § 51.8 which provides that no disclosure is required in adjudicatory proceedings unless the Department states an intent or the possibility of the revocation of a license or permit. This matter does not involve the revocation of a license or permit. Therefore, the Department was under no obligation to produce any disclosure documents. At my request, however, the Department presented evidence to establish the process used by the Department to evaluate the applications for registration, by providing the testimony of three witnesses and obtaining the admission of several documents into evidence.

The Department offered the testimony of Nicole K. Quackenbush, Pharm.D., the Director of the Medical Marijuana Program; Amanda Wilson, a Health Program Administrator 2 with the Program; and Ann C. Walsh, M.D., Ph.D., the Associate Director for Medical Affairs in the Department’s Wadsworth Center. These three witnesses played integral roles in the development of the application for registration and the evaluation process. Their testimony provided a thorough explanation of the scoring methodology which the evaluators were required to utilize when evaluating the RO applications.

The following documents related to the application evaluation process were among the documents offered by the Department and admitted into evidence:

- Department Ex. 1 – Instructions for the Application for Registration as a RO
- Department Ex. 2 – DOH-5138 – Form for the Application for Registration as a RO
- Department Ex. 3 – DOH-5145 – Appendix A Form
- Department Ex. 4 – DOH-5146 – Appendix B Form
- Department Ex. 5 – Questions and Answers on Application
- Department Ex. 6 – Application Evaluation Process Flowchart
- Department Ex. 7 – Application Review Assignments
- Department Ex. 8a – RO Evaluation Tool

- Department Ex. 8b – Evaluation Ratings: Explanation & Definitions
- Department Ex. 8c – Real Property Evaluation Criteria
- Department Ex. 8d - Transportation and Distribution Evaluation Criteria
- Department Ex. 8e – Security Evaluation Criteria
- Department Ex. 8f – Miscellaneous Evaluation Criteria
- Department Ex. 8g – Organizational Structure Evaluation Criteria
- Department Ex. 8h – Manufacturing Evaluation Criteria
- Department Ex. 8i – Staffing Evaluation Criteria
- Department Ex. 8j – Sales and Dispensing Evaluation Criteria
- Department Ex. 8k – Architectural Program Evaluation Criteria
- Department Ex. 8l – Geographic Distribution of Dispensing Facilities Evaluation Criteria
- Department Ex. 8m – Financial Evaluation Criteria
- Department Ex. 9 – Application Pass/Fail Checklist
- Department Ex. 10 – Applicant Information Checklist
- Department Ex. 14a – Scoresheets for the 43 RO Applications
- Department Ex. 14c – Summary of the 43 RO Application Scores and Ranks
- Department Ex. 14d – Evaluator Scoresheets for the 43 RO Applications
- Department Ex. 15 – Summary of Evaluation Process, Criteria, Weights and Results
- Department Ex. 16 – Steps to Access Applications and Evaluations on Shared Drive
- Department Ex 18 – RO Application Evaluation Training Agenda

The only reference to creating a right to a hearing contained in the Medical Marihuana Act is PHL § 3365(3)(b), which states that an applicant may demand a hearing if notified that the Commissioner is not satisfied that that the applicant should be issued a registration. The Department used a scoring methodology to determine which of the 43 applicants would be granted a registration. The Department initially granted registrations to the five applicants with the highest score and subsequently granted registration to the five applicants with the next highest score. The Department did not issue written notifications to the Petitioners or the other unsuccessful applicants regarding factors upon which further evidence was required as described in PHL § 3365(3)(b), and the Petitioners requested this hearing based on the Department's failure to either provide this notification or grant a registration. The scope of this hearing has been limited to whether the Department's scoring methodology was consistent with the Medical Marihuana Act (PHL §§ 3360-3369-e) and the Department's regulations (10 NYCRR Part 1004), and whether the scoring methodology was properly applied.

The first aspect of this inquiry is whether the Department's methodology was consistent with the statute and the regulations. Since the Department has already provided the testimony of three witnesses and documentation including the application, instructions, criteria, weights and scoresheets, I find that the evidence already in the record is sufficient to establish the scoring methodology utilized by the Department in evaluating the applications. None of the additional evidence being requested is necessary for the Petitioners to be heard on whether this methodology was inconsistent with the Department's statute and regulations.

The second aspect of this inquiry is whether the Department's methodology was properly applied. None of the additional documents being requested by Petitioners NYMG, CCCofNY and

HHE are necessary for the Petitioners to be heard on whether the Department's methodology was properly applied to their own application. Instead, this documentation would only be relevant if the scope of this hearing were extended to include a review of the ten successful RO applicants which are not a party to this proceeding. For the following reasons including the prohibition against requiring disclosure in these proceedings, the privileged information contained in the applications of the ten successful RO applicants and the limitations of PHL §§ 3365(3)(b) and 3371, I have decided that the scope of this hearing should not be extended in that manner.

The applications of all 43 RO applicants are available to the Petitioners on the Department's website with redactions made pursuant to FOIL by the Department's Record Access Office. According to the Department's website, the applications were redacted because they contained information that was personal, trade secret, critical infrastructure information, or security related information that could endanger the life or safety of any person. However, Petitioners NYMG, CCONY and HHE have now requested that I issue subpoenas for the applications of the 10 current ROs, revealing the redactions made under FOIL (except for the removal of social security numbers EINs, personal addresses, telephone numbers, bank account numbers, passwords and fingerprints).

Aside from the issue of redactions made to these applications pursuant to FOIL, I also note that PHL § 3371 affords additional protections against the Department's release of information related to manufacturing processes, trade secrets and formulas. Due to these restrictions, I have gone on to consider whether Petitioners NYMG, CCONY and HHE have shown that their standing as parties to this administrative hearing warrants disclosure of the protected material of the 10 current RO applicants which are not a party to this administrative hearing. On this issue, I have also considered the following letters from five of the non-party ROs whose protected information has been requested:

- Letter dated April 18, 2018, from Garfunkel Wild, P.C., by James E. Dering, Esq., representing non-party PharmaCann, LLC.
- Letter dated April 20, 2018, from Loeb & Loeb, LLP, by Frank D. D'Angelo, Esq., representing non-party Pallia Tech NY, LLC.
- Letters dated April 23 and 26, 2018, from Duane Morris, by Jerome T. Levy, Esq., representing non-party Fiorello Pharmaceuticals, Inc.
- Letter dated April 25, 2018, from Shansky Law Group, LLP, by Colin R. Hagan, Esq., representing non-party Valley Agriceuticals, LLC.
- Letter dated May 1, 2018, from Couch White, by Jennifer Kavney Harvey, Esq., representing non-party Etain, LLC.

These letters set forth the reasons why these non-parties are opposed to the disclosure of privileged trade secret and confidential information contained in their applications.

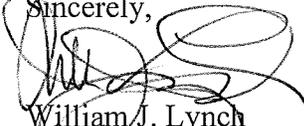
I considered a suggestion that I issue a protective order which would prevent the Petitioners from further disclosing any privileged information which they might receive as a party to this hearing; however, the non-party ROs are competitors of the Petitioners, and I fail to see how a protective order in this instance would prevent economic and other harm to the interests of these non-parties if their unredacted applications are disclosed. In addition, PHL § 3371 specifically

prohibits the disclosure of a manufacturing process, a trade secret or a formula. As such, I conclude that PHL § 3365(3)(b) can only be read as consistent with PHL § 3371 if the second assessment is limited to whether the Department's methodology was properly applied to the Petitioners' own applications. Therefore, the material now being sought is not essential to a determination of Petitioners' rights, and the unredacted portions of the applications made by other organizations are not relevant to this proceeding.

Finally, I have considered whether any of the requested evidence is necessary for the Petitioners to be heard on whether the Department's methodology was properly applied to their own applications. The only item which potentially falls into this category is the testimony of the 15 requested witnesses who were involved in the Department's scoring of the individual sections of the RO applications. However, any testimony by these additional Department employees and former employees would be cumulative on the relevant issues because the criteria, weights, scoresheets and conversion factors are already in evidence, and Petitioners can establish any failure by these potential witnesses to follow the Department's methodology without their testimony.

There are seven Petitioners remaining in this proceeding. Some have requested that they not be required to attend on a future hearing day when another Petitioner is presenting a witness or argument, and I have decided to grant that request. I will also provide the parties an opportunity to make a written submission on the issues.

Please let me know if you are available on the following dates and whether you wish to attend on all dates or wish to be excused when other Petitioners are presenting: September 25, 26, 27, 28, and October 1, 2, 3, 4, 5, 9, 10, 11 and 12.

Sincerely,

William J. Lynch
New York State Department of Health
Bureau of Adjudication
Riverview Center
150 Broadway - Suite 510
Menands, New York 12204

Appendix A

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Good Green Group LLC

Mitch Baruchowitz, Managing Member
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Rye, NY 10508

Mitch@meridacap.com
Hudson Health Extracts LLC

EXHIBIT K

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: DEBRA HOTALING
C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

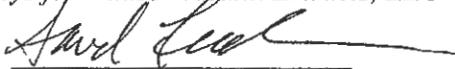
WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

WE COMMAND YOU, as authorized under State Administrative Procedure Act ("SAPA") §304(2), pursuant to CPLR §§ 2302, 2305, and 3120, that all business and excuses being laid aside, you appear before Administrative Law Judge William J. Lynch of the New York State Department of Health, located at Riverview Center, 150 Broadway, Fifth Floor, Harvest Room, Albany, New York, 11204, on the **30th day of November, 2018, at 10:00 A.M.**, and at any recessed adjourned date thereof.

PLEASE TAKE NOTICE, that failure to comply with this subpoena ad testificandum is punishable as a contempt of Court and shall make you liable to the person on whose behalf this subpoena duces tecum was issued for a penalty not to exceed fifty (\$50.00) dollars and all damages sustained by reason of your failure to comply, as well as all further penalties prescribed by law.

Dated: November 20, 2018

FEUERSTEIN KULICK LLP
Attorneys for Hudson Health Extracts, LLC

By: 
David Feuerstein, Esq.
205 E. 42nd Street, 20th Floor
New York NY, 10017
(646)768-0591

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: JUSTIN HUBER
C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

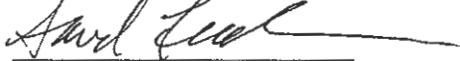
WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

WE COMMAND YOU, as authorized under State Administrative Procedure Act ("SAPA") §304(2), pursuant to CPLR §§ 2302, 2305, and 3120, that all business and excuses being laid aside, you appear before Administrative Law Judge William J. Lynch of the New York State Department of Health, located at Riverview Center, 150 Broadway, Fifth Floor, Harvest Room, Albany, New York, 11204, on the **30th day of November, 2018, at 10:00 A.M.**, and at any recessed adjourned date thereof.

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Dated: November 20, 2018

FEUERSTEIN KULICK LLP
Attorneys for Hudson Health Extracts, LLC

By: 
David Feuerstein, Esq.
205 E. 42nd Street, 20th Floor
New York NY, 10017
(646)768-0591

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: JAMES MILLER
C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

WE COMMAND YOU, as authorized under State Administrative Procedure Act ("SAPA") §304(2), pursuant to CPLR §§ 2302, 2305, and 3120, that all business and excuses being laid aside, you appear before Administrative Law Judge William J. Lynch of the New York State Department of Health, located at Riverview Center, 150 Broadway, Fifth Floor, Harvest Room, Albany, New York, 11204, on the **30th day of November, 2018, at 10:00 A.M.**, and at any recessed adjourned date thereof.

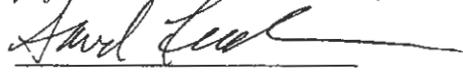
PLEASE TAKE NOTICE, that failure to comply with this subpoena ad testificandum is punishable as a contempt of Court and shall make you liable to the person on whose behalf this subpoena duces tecum was issued for a penalty not to exceed fifty (\$50.00) dollars and all damages sustained by reason of your failure to comply, as well as all further penalties prescribed by law.

Dated: November 20, 2018

FEUERSTEIN KULICK LLP

Attorneys for Hudson Health Extracts, LLC

By:



David Feuerstein, Esq.
205 E. 42nd Street, 20th Floor
New York NY, 10017
(646)768-0591

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: GEORGE STATHIDIS

C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

WE COMMAND YOU, as authorized under State Administrative Procedure Act ("SAPA") §304(2), pursuant to CPLR §§ 2302, 2305, and 3120, that all business and excuses being laid aside, you appear before Administrative Law Judge William J. Lynch of the New York State Department of Health, located at Riverview Center, 150 Broadway, Fifth Floor, Harvest Room, Albany, New York, 11204, on the **30th day of November, 2018, at 10:00 A.M.**, and at any recessed adjourned date thereof.

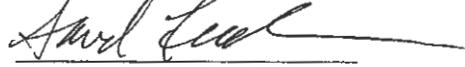
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Dated: November 20, 2018

FEUERSTEIN KULICK LLP

Attorneys for Hudson Health Extracts, LLC

By:



David Feuerstein, Esq.
205 E. 42nd Street, 20th Floor
New York NY, 10017
(646)768-0591

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marijuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: STEPHEN SUMNER

C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marijuana;

WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

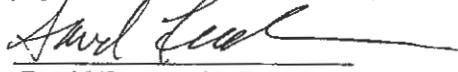
WE COMMAND YOU, as authorized under State Administrative Procedure Act ("SAPA") §304(2), pursuant to CPLR §§ 2302, 2305, and 3120, that all business and excuses being laid aside, you appear before Administrative Law Judge William J. Lynch of the New York State Department of Health, located at Riverview Center, 150 Broadway, Fifth Floor, Harvest Room, Albany, New York, 11204, on the **30th day of November, 2018, at 10:00 A.M.**, and at any recessed adjourned date thereof.

PLEASE TAKE NOTICE, that failure to comply with this subpoena ad testificandum is punishable as a contempt of Court and shall make you liable to the person on whose behalf this subpoena duces tecum was issued for a penalty not to exceed fifty (\$50.00) dollars and all damages sustained by reason of your failure to comply, as well as all further penalties prescribed by law.

Dated: November 20, 2018

FEUERSTEIN KULICK LLP

Attorneys for Hudson Health Extracts, LLC

By: 

David Feuerstein, Esq.
205 E. 42nd Street, 20th Floor
New York NY, 10017
(646)768-0591

STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: DENISE PLATT

C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

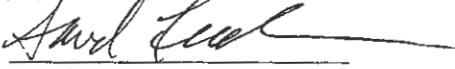
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Dated: November 20, 2018

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STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
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Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: DIANE CHRISTENSEN
C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

WHEREAS, there is a Hearing being held before the Adjudication Bureau of the New York State Department of Health (the "Department"), pursuant to Section 3365(3)(b) of the Public Health Law ("PHL") and Section 1004.6(d) of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York ("NYCRR"), challenging the Department's decisions to not select the Petitioners for registration as registered organizations under PHL §§ 3364 and 3365 and 10 NYCRR §§ 1004.5 and 1004.6 for the purposes of Acquiring, Possessing, Manufacturing, Selling, Delivering, Transporting, Distributing, or Dispensing Marihuana;

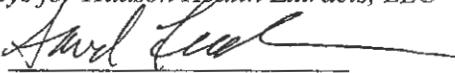
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Dated: November 20, 2018

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STATE OF NEW YORK
DEPARTMENT OF HEALTH

In the Matter of,

Unselected Applications for Registration as
Registered Organizations to Manufacture and
Dispense Medical Marihuana under New York's
Compassionate Care Act

**SUBPOENA
AD TESTIFICANDUM**

THE PEOPLE OF THE STATE OF NEW YORK

TO: JAMES GOTTFREY

C/O New York State Department of Health
Corning Tower
Empire State Plaza
Albany, NY 12237

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WHEREAS, You have information that is necessary for this Hearing and necessary for determination of whether the Department complied with the applicable law in selecting the Registered Organizations and/or whether the Department properly conducted its selection process in selecting the Registered Organizations;

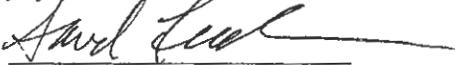
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Overview

Pursuant to Public Health Law (PHL) § 3365(9), the Commissioner of the New York State Department of Health ("Department") shall register up to five applicants as registered organizations to manufacture and dispense approved medical marijuana products in New York State. In accordance with PHL § 3365(9), the Department will register five applicants as registered organizations, and is accepting applications from April 27, 2015 through and including May 29, 2015 for this purpose.

Each applicant must submit two fees with its application: a non-refundable application fee in the amount of \$10,000, and a registration fee in the amount of \$200,000. The fees are payable together or separately by certified check to the "New York State Department of Health."

The \$200,000 registration fee will be refunded to the applicant only if the applicant is not issued a registration.

Registrations issued by the Department shall be valid for a period of two (2) years. The Department will evaluate all completed applications received on or before the deadline in accordance with the criteria set forth in PHL § 3365(3) and Title 10 of the New York Code of Rules and Regulations (NYCRR) § 1004.6.

Application Timeline

Table with 2 columns: Event, Date. Rows include Application Window Opens (04/27/2015), Deadline for Submission of Application Questions (05/05/2015 4:00 PM ET), Deadline for Department Response to Application Questions (05/14/2015), Deadline for Department Receipt of Applications (05/29/2015), Registrations Issued (Estimated Timeframe) (Approximately July 2015).

Important Notices

- 1. The Department shall only review completed applications received by the above Deadline for Department Receipt of Applications and for which the application and registration fees have been submitted. Any cost incurred by the applicant in connection with the application, including but not limited to obtaining or creating the information, documents, materials and certifications required by the application, shall not be a charge upon the Department.
2. All notices from the Department to an applicant regarding an application that has been submitted will be sent to the email address that the applicant provides on the registration application Form DOH-5138. Applicants must immediately notify the Department of any change of address by email only at mmp@health.ny.gov with the subject line "Registered Organization Address Change."



3. The applicant shall be under a continuing duty to report to the Department any change in facts or circumstances stated in the application or any newly-discovered or occurring fact or circumstance which is required to be included in the application.
4. The applicant shall verify the truth and accuracy of the information and documentation submitted in its application. Any material omissions, material errors, misrepresentations, or failure to provide any requested information may result in the denial of the application or other action as may be allowed by law. The Department may, in its discretion, reject an application if it determines that information contained therein is not true and accurate.
5. An applicant that is issued a registration to operate as a registered organization shall be subject to and operate in accordance with Title V-A of Article 33 of the PHL and 10 NYCRR Part 1004 and all other applicable state and local laws and regulations.

Questions and Answers

All questions about the application or application process must be submitted to the Department by May 5, 2015. Questions must be submitted **by email only** at mmp@health.ny.gov with the subject line "Registered Organization Application Question" and include the reference to the application section and field number, where applicable. Applicants should identify and bring any questions to the Department's attention as soon as possible. The Department reserves the right to contact applicants for clarification and/or additional information concerning their questions. The Department will evaluate questions as they are received up until the deadline for submission of questions. Responses to all questions will be posted to the Department's web page (https://www.health.ny.gov/regulations/medical_marijuana/) by May 14, 2015. No questions will be accepted by telephone or means other than through the email address noted above.

Acceptance of Applications

The Department will not accept for consideration any application which is not complete by May 29, 2015 4:00 PM ET. An application is not complete unless the following have been received by the Department:

1. The certified check(s) made out to the "New York State Department of Health" totaling \$210,000, consisting of the \$10,000 application fee (non-refundable) and the \$200,000 registration fee (refundable if the Department does not select the applicant as a Registered Organization); and
2. The registration application Form DOH-5138, together with all attachments, appendices and supporting documentation, including:
 - a. Attachments "A" through "M" as required by Section I;



- b. The applicant's chief executive officer duly authorized by the board of a corporate applicant, or a general partner or owner of a proprietary applicant, has signed the application and the signature is notarized;
- c. Appendix A – Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members (Form DOH-5145); and
- d. Appendix B – Architectural Program (Form DOH-5146).

Criteria for Consideration of Applications

The Department shall review all information and documentation submitted by the applicant, and consider the criteria set forth in PHL § 3365 and 10 NYCRR § 1004.6, in making its determination. The applicant's submissions should demonstrate how it will meet said criteria, including but not limited to:

1. the ability to manufacture approved medical marijuana products, each with a consistent cannabinoid profile (the concentration of total tetrahydrocannabinol (THC) and total cannabidiol (CBD) will define the brand), and each able to pass the required quality control testing as further described in 10 NYCRR § 1004.11;
2. the ability to produce sufficient quantities of approved medical marijuana products, as further described in 10 NYCRR § 1004.11, as necessary to meet the needs of certified patients;
3. the ability to maintain effective control against diversion of marijuana and medical marijuana products as further described in 10 NYCRR § 1004.13;
4. the ability to comply with all applicable state and local laws and regulations;
5. that, if selected, the applicant is ready, willing, and able to properly carry on the activities set forth in 10 NYCRR Part 1004;
6. possession of, or the right to use, sufficient real property, buildings, and equipment to properly carry on the activity described in its operating plan, or in the alternative, the applicant has posted a bond in the amount of \$2,000,000;
7. that it is in the public interest that such registration be granted to the applicant;
8. that the applicant's four proposed dispensing facilities are geographically distributed. To be geographically distributed, the proposed dispensing facilities of an applicant must be located in multiple counties across New York State to best serve certified patients in the Medical Marijuana Program state-wide. Geographic distribution will not be demonstrated by the applicant if the proposed dispensing facilities of the applicant are all concentrated in counties of New York State that are neighboring or in close proximity.



-
9. the moral character and competence of board members, officers, managers, owners, partners, principal stakeholders, directors, and members of the applicant's organization;
 10. the applicant's proposed operating plan and suitability of the proposed manufacturing and dispensing facilities, including but not limited to the suitability of the location and the architectural and engineering design of the proposed facilities; and
 11. the applicant has entered into a labor peace agreement, as defined in PHL § 3360(14), with a bona-fide labor organization that is actively engaged in representing or attempting to represent the applicant's employees.

Note: In demonstrating how such criteria are met, the information and submissions made as part of the application must contain specifics to show compliance with the applicable requirements of Title V-A of Article 33 of the PHL and 10 NYCRR Part 1004.

The Department reserves the right to interview any applicant, and/or any individuals identified in an application, to ensure the accuracy and completeness of an application, and to use the information obtained from any such interview in considering the application pursuant to the statutory and regulatory criteria

The applicant shall allow reasonable access to the Department and/or its authorized representatives for the purpose of conducting an on-site survey or inspection of the applicant's proposed manufacturing and/or dispensing facilities. An entity selected as a registered organization is subject to ongoing audits by the Department, which may include unannounced site visits. The registered organization shall provide reasonable access to the Department of its facilities, books, records, personnel, etc.

Clarification Process

The Department reserves the right to contact any applicant after the submission of its application for the purpose of clarifying any item submitted in its application or to request additional information to ensure mutual understanding. This contact may include written questions, interviews, site visits, or requests for corrective pages in the application. Responses must be submitted to the Department within the time specified in the request. As applicable, clarifications will be treated as addenda to an application. Failure to comply with a request for additional information may result in rejection of the application as noncompliant. Nothing herein shall be deemed to extend the deadline for Department Receipt of completed applications.



Application Submission Instructions

1. Complete Form DOH-5138 and include all necessary relevant documents for each item requested in the application. All attachments provided by the applicant must be clearly labeled as to which section the information corresponds so that it is clear to the Department that all requested information is provided.
2. Complete Appendix A: Affidavit for Board Members, Officers, Managers, Owners, Partners, Principal Stakeholders, Directors, and Members Form DOH-5145. For board members, officers, managers, owners, partners, directors, and members of the applicant that are not natural persons, Appendix A must be completed by each board member, officer, manager, owner, partner, director and member of that entity. For example, if one of the owners identified in the application is a corporation, Appendix A must be completed by each of the corporation's board members, officers, owners, partners, principal stakeholders, directors, and members. If an interest or ownership in the entity is not held by a natural person, Appendix A must be completed going back to the level of ownership by a natural person (principal stakeholders).
3. Complete Appendix B: Architectural Program Form DOH-5146.
4. Submit the following items to the address below by the application deadline (the Department will only review completed applications received by the application deadline):
 - a. one original and nine copies of the completed application FORM DOH-5138, Appendix A Form DOH-5145, Appendix B Form DOH-5146, and all attachments required by the application, all of which must be single-sided and securely bound;
 - b. a CD, DVD, or USB flash drive containing an electronic version of your completed application, Appendix A, Appendix B, and all attachments in a searchable PDF file; and
 - c. certified checks payable to the "New York State Department of Health" in the amounts of \$10,000 for the non-refundable application fee and \$200,000 for the conditionally refundable registration fee; or a certified check payable to the "New York State Department of Health" in the amount of \$210,000 for both fees.

ADDRESS: **New York State Department of Health**
 Bureau of Narcotic Enforcement
 Medical Marijuana Program
 150 Broadway
 Albany, NY 12204

Applicants who wish to hand deliver their applications must notify the Department by email at mmp@health.ny.gov a minimum of twenty-four (24) hours in advance of the anticipated delivery date to make delivery arrangements and include "Registered Organization Application Delivery Request" in the subject line.



Freedom of Information Law

Disclosure of information contained in submitted applications is subject to the laws of the State of New York, including the Freedom of Information Law (FOIL) contained in Article 6 of the Public Officers Law. **Information constituting trade secrets or critical infrastructure information for purposes of FOIL should be clearly marked and identified as such by the applicant upon submission. Each page containing such information should contain a footer notifying the Department that the material on the page is requested to be exempt from disclosure under FOIL pursuant to one of the exceptions referred to above. Applicants should not merely state generally that the application is proprietary in nature and, therefore, not subject to release to third parties. Determinations as to whether the materials or information may be withheld from disclosure will be made in accordance with Public Officers Law § 87.**