

**STATE OF FLORIDA
DEPARTMENT OF HEALTH
OFFICE OF COMPASSIONATE USE**

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LOOP'S NURSERY & GREENHOUSES,
INC.,

Petitioner,

Case No. 15-_____

v.

STATE OF FLORIDA, DEPARTMENT OF
HEALTH, OFFICE OF COMPASSIONATE USE;
CHESTNUT HILL TREE FARM, LLC., and
SAN FELASCO NURSERIES, INC.,

Respondents,

_____ /

PETITION FOR FORMAL ADMINISTRATIVE HEARING

Petitioner, Loop's Nursery & Greenhouses, Inc. ("Loop's Nursery" or "Loop's"), by and through its undersigned counsel, and pursuant to sections 120.569 and 120.57(1), Florida Statutes, and Rule 28-106.201, Florida Administrative Code, files this Petition for Formal Administrative Hearing to contest the November 23, 2015 preliminary agency action by the Florida Department of Health, Office of Compassionate use (the "Department" or "OCU") with respect to the Department's initial decision regarding the approval, pursuant to the Medical Cannabis Act of 2014, Section 381.986, Florida Statutes, of a Dispensing Organization for the Northeast Region and in support thereof states as follows:

PRELIMINARY STATEMENT

1. The application filed by Loop's Nursery to serve as the Dispensing Organization for the Northeast Region is the highest scored application that satisfies all mandatory statutory and regulatory requirements for approval. Loop's Nursery is the only applicant in the Northeast Region capable of timely establishing the safest, most effective, highest quality and most

sustainable low-THC dispensing operation and organization. Loop's Nursery's application is best able to further the statutory objective of ensuring accessibility and availability of low-THC cannabis to patients.

2. The Compassionate Medical Cannabis Act of 2014 (also known as the "Charlotte's Web" law) (the "Act") requires OCU to select "the most dependable, most qualified dispensing organizations to cultivate, process, and dispense low-THC cannabis as prescribed by physicians." Costa Farms, LLC v. Department of Health, DOAH Case No. 14-4296RP, ¶ 93 (Fla. DOAH Nov. 14, 2014). The application form incorporated by reference into the Department's rules acknowledges this statutory mandate, and states on page one:

This Application for Low-THC Cannabis Dispensing Organization Approval (Application) is designed to allow the Florida Department of Health, Office of Compassionate Use (OCU) to fulfill its statutory duty to select the five Dispensing Organizations meeting the requirements of section 381.986(5)(b), F.S. (Statute), best able to further the statutory objective of ensuring accessibility and availability of Low-THC cannabis to patients. This has been further clarified to mean that OCU must choose the most dependable, most qualified dispensing organizations that can consistently deliver high-quality Derivative Products.

Loop's application is the only application in the Northeast Region that satisfies all mandatory statutory and regulatory criteria for approval. Loop's is the most dependable and most qualified applicant, and is the only applicant with the current operational infrastructure to rapidly and consistently produce high quality low-THC derivative products and to make such products widely available and accessible to qualified patients within the Northeast Region.

3. The application filed by Chestnut Hill Tree Farm, LLC ("Chestnut Hill") was preliminarily approved by OCU but has material defects that require disqualification of Chestnut Hill as an applicant. Chestnut Hill's application fails to meet mandatory statutory and regulatory

criteria. The deficiencies in Chestnut Hill's status as an applicant include, but are not limited to, Chestnut Hill's failure to satisfy the statutory requirement in section 381.986(5) (d), Florida Statutes, namely, of having continuously operated as a Florida registered nursery for at least thirty (30) continuous years. According to corporate records maintained by the Florida Secretary of State, the applicant, Chestnut Hill, was corporately formed and organized in 2005, only 10 years ago. Thus, it cannot meet the statutory legal requirement to have continuously operated as a nursery for thirty (30) years. In addition, Chestnut Hill's application contains an intentional material misrepresentation of fact regarding its ability to offer qualified patients the Charlotte's Web strain of low-THC cannabis. Chestnut Hill misrepresented that it would and could provide the Charlotte's Web strain of low-THC cannabis to patients, when it does not have the ability to do so. Chestnut Hill's acknowledges, in pertinent part at page 11 of the application that, "I understand that any misrepresentation of the facts in this application ... is grounds for denial or revocation of the Low-THC Cannabis Dispensing Organization Approval." (emphasis added). Chestnut Hill also lacks the physical and technological capability to meet the 75 calendar day deadline of February 6, 2016 to gain approval from the Office of Compassionate Use for cultivation of safe, appropriate, and efficacious low-THC cannabis plants. Chestnut Hill's deficient application should automatically disqualify Chestnut Hill as a candidate for approval as a Dispensing Organization under the Act.

4. In addition, the Department correctly disqualified the application filed by San Felasco Nurseries, Inc. ("San Felasco"), based on San Felasco's failure to satisfy the mandatory Level II background screening and personnel requirements set forth in section 381.986, Florida Statutes. A key member (or members) of the San Felasco team did not pass the Level II background screening, and San Felasco's application was properly disqualified.

PARTIES

5. Petitioner Loop's Nursery & Greenhouses, Inc. was founded in Florida as a professional greenhouse grower in 1949, and was organized as a corporation under the laws of Florida in 1970. Loop's Nursery has continuously operated as a nursery for over 30 years and has done so pursuant to a valid Certificate of Registration issued by the State of Florida, Department of Agriculture and Consumer Services pursuant to section 581.131, Florida Statutes.

6. Loop's Nursery is a Florida greenhouse pioneer, having led the industry in advanced cultivation practices, such as drip irrigation to increase growing efficiency and the use of blackout shade cloths to maximize yield. Loop's Nursery today specializes in greenhouse grown, flowering potted plants and has cultivated more than 400,000 plants annually since the early 1980's. Loop's Nursery harvested over 3.6 million plant clones in 2014 alone.

7. Loop's Nursery has followed good agriculture practices and best management practices over their decades of operation. They are advised by the Stanley Brothers from Colorado on implementation of good agricultural practices specific to low-THC cannabis. Loop's Nursery and the Stanley Brothers have developed and implemented numerous Standard Operating Procedures relating to low-THC cannabis. Additionally, Loop's Nursery currently works with breeders from all over the world to improve plant traits, viability, sustainability and efficiency of operations. Approximately seventy percent of the plants from Loop's Nursery are sold in supermarkets throughout the southeast and along the east coast, five percent go to retail nurseries and florists, and approximately twenty-five percent go to wholesalers and brokers. The majority of plants cultivated by Loop's Nursery are non-native to Florida.

8. Loop's Nursery is operated by a qualified nurseryman, as defined in section 581.011, Florida Statutes, and has received a number of awards and recognition for best practices and leadership within the agricultural industry.

9. Loop's Nursery currently has state-of-the art greenhouses consisting of 650,000 square feet. These greenhouses are fully automated, including but not limited to temperature and humidity control, and employ 3 styles of auto-irrigation, auto-blackout shade cloths and supplemental lighting. Loop's Nursery is currently located in St. Johns County on 160 acres with 84 undeveloped acres available for immediate expansion. Loop's Nursery currently has the existing land, infrastructure, personnel, and standard operating procedures to begin cultivation of low-THC cannabis within ten days of licensure as a Dispensing Organization.

10. Loop's Nursery retains a Ph.D. level chemist with experience in analytical chemistry, organic chemistry and microbiology applicable to the processing and analytical testing of low-THC cannabis. Loop's also retained a team member who holds both cGMP and GHP certifications, and is qualified to implement American Herbal Products Association (AHPA) for quality control of low-THC cannabis. Loop's existing 6,400 square foot structure in Duval County, Florida will be used for low-THC cannabis processing and as an analytical laboratory. This facility will be completed and ready for operation within 120 days from the date of licensure.

11. Loop's Nursery has secured eight satellite dispensing locations throughout Florida and will be opening four additional facilities immediately after licensure to ensure proper, state-wide patient access to low-THC cannabis products. Loop's dispensing plan ensures that 62% of the Florida population will have a dispensary in their county and 92% of the Florida population will be within 50 miles of a Loop's dispensary.

12. Loop's Nursery is the only nursery currently licensed in Florida to legally cultivate and process the strain of low-THC cannabis known as "Charlotte's Web." "Charlotte's Web" has been recognized internationally as a safe, efficacious cannabis strain that was specifically developed and refined to treat the medical conditions that are the subject of section 381.986, Florida Statutes. "Charlotte's Web" has been recommended by physicians and successfully employed to help relieve the symptoms of epilepsy, muscle spasms and cancer since 2009. Loop's right to cultivate, process, and make available "Charlotte's Web," is protected under Florida trademark law and existing Florida trademarks.

13. Loop's Nursery & Greenhouses, Inc.'s headquarters are located at 4844 Race Track Road, St. John's, Florida, 32259. For purposes of service of all required notices and papers in this proceeding, Loop's Nursery & Greenhouse's address is that of the undersigned counsel.

14. Respondent Department of Health, Office of Compassionate Use is the state agency authorized to approve dispensing organizations pursuant to section 381.986, Florida Statutes. Respondent's mailing address is 2585 Merchants Row Blvd., Tallahassee, Florida, 32399.

15. Respondent, Chestnut Hill Tree Farm ("Chestnut Hill"), is a Florida limited liability company, whose principal place of business is 15105 Northwest 94th Avenue, Alachua, Florida, 32615.

16. Respondent, San Felasco Nurseries, Inc. ("San Felasco"), is a Florida corporation whose principal place of business is 7315 Northwest 126th Street, Gainesville, Florida, 32653.

PROCEDURAL BACKGROUND

17. In 2014, the Florida Legislature enacted the Compassionate Medical Cannabis Act of 2014, at Chapter 2014-157, Laws of Florida (the "Act.") The Act was signed into law on June

16, 2014 and is now codified in section 381.986, Florida Statutes. The Act authorizes the cultivation and processing of low-THC cannabis by an approved Dispensing Organization within the state of Florida, for the purpose of dispensing low-THC cannabis to qualified patients in Florida pursuant to a valid physician order. The Act provides for the regulation and use of low-THC cannabis to provide relief for certain patients with debilitating diseases, when ordered by a Florida physician. The Act authorizes licensed physicians to recommend low-THC cannabis, or “Derivative Product,” for qualified patients under specified conditions, primarily those suffering from cancer, epilepsy or other conditions that produce severe and persistent seizures or muscle spasms.

18. For purposes of the Act, “Low-THC Cannabis” means “a plant of the genus Cannabis, the dried flowers of which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight; the seeds thereof; the resin extracted from any part of such plant; or any compound, manufacture, salt, derivative, mixture, or preparation of such plant or its seeds or resin that is dispensed only from a dispensing organization.”

19. The Act directs the Department to “authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida.”

20. Section 381.986, Florida Statutes, embodies both the statutory authority for and the law implemented by the Proposed Rules. Section 381.986 states, in pertinent part:

(5) DUTIES OF THE DEPARTMENT —By January 1, 2015, the department shall:

(a) Create a secure, electronic, and online compassionate use registry for the registration of physicians and patients as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization in order to verify patient authorization for low-THC cannabis and record the low-THC cannabis dispensed. The registry must prevent an active registration of a patient by multiple physicians.

(b) Authorize the establishment of five dispensing organizations to ensure reasonable statewide accessibility and availability as necessary for patients registered in the compassionate use registry and who are ordered low-THC cannabis under this section, one in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. The department shall develop an application form and impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering this section. An applicant for approval as a dispensing organization must be able to demonstrate:

1. The technical and technological ability to cultivate and produce low-THC cannabis. The applicant must possess a valid certificate of registration issued by the Department of Agriculture and Consumer Services pursuant to s. 581.131 that is issued for the cultivation of more than 400,000 plants, be operated by a nurseryman as defined in s. 581.011, and have been operated as a registered nursery in this state for at least 30 continuous years.
2. The ability to secure the premises, resources, and personnel necessary to operate as a dispensing organization.
3. The ability to maintain accountability of all raw materials, finished products, and any byproducts to prevent diversion or unlawful access to or possession of these substances.
4. An infrastructure reasonably located to dispense low-THC cannabis to registered patients statewide or regionally as determined by the department.
5. The financial ability to maintain operations for the duration of the 2-year approval cycle, including the provision of certified financials to the department. Upon approval, the applicant must post a \$5 million performance bond.
6. That all owners and managers have been fingerprinted and

have successfully passed a level 2 background screening pursuant to s. 435.04.

7. The employment of a medical director who is a physician licensed under chapter 458 or chapter 459 to supervise the activities of the dispensing organization.

(c) Monitor physician registration and ordering of low-THC cannabis for ordering practices that could facilitate unlawful diversion or misuse of low-THC cannabis and take disciplinary action as indicated.

(d) Adopt rules necessary to implement this section.

(6) DISPENSING ORGANIZATION —An approved dispensing organization shall maintain compliance with the criteria demonstrated for selection and approval as a dispensing organization under subsection (5) at all times. Before dispensing low-THC cannabis to a qualified patient, the dispensing organization shall verify that the patient has an active registration in the compassionate use registry, the order presented matches the order contents as recorded in the registry, and the order has not already been filled. Upon dispensing the low-THC cannabis, the dispensing organization shall record in the registry the date, time, quantity, and form of low- THC cannabis dispensed.

21. Pursuant to section 381.986, Florida Statutes, the Department adopted Rule 64-4, Florida Administrative Code, which establishes a regulatory framework to implement the Act by, among other things, creating dispensing organization application, approval, and authorization procedures. Rule 64-4.001 sets forth definitions of key terms. Rule 64-4.002 delineates the requirements for the dispensing organization application and approval process, including the application fee, required criminal background screening, and criteria pertaining to how an applicant may demonstrate that it best meets the statutory criteria to become a dispensing organization.

Rule 64-4.002(5), in pertinent part, states that:

(a) The department will substantively review, evaluate, and score applications using Form DH8007-OCU-2/2015, "Scorecard for Low-THC Cannabis Dispensing Organization Selection" herein incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-05461>. The department's substantive review will be completed by:

1. Director of the Office of Compassionate Use;
2. A member of the Drug Policy Advisory Council appointed by the State Surgeon General; and,
3. A Certified Public Accountant appointed by the State Surgeon General.

(b) Each reviewer will independently review each application and score using Form DH8007-OCU-2/2015, "Scorecard for Low-THC Cannabis Dispensing Organization Selection." Scorecards from each reviewer will be combined to generate an aggregate score for each application. The Applicant with the highest aggregate score in each dispensing region shall be selected as the region's Dispensing Organization.

(c) In the event of a tie in a region, each reviewer will re-review the tied applications and select a winning application. The department will approve the application selected by the majority of the reviewers.

(d) In the event one nursery receives the high score in multiple regions, one of which is the region represented by the address on the nursery's certificate of registration, the Applicant will be approved for that region, and the second highest scored Applicant will be approved for the other region(s). In the event one nursery receives the high score in multiple regions, none of which is the region represented by the address on the nursery's certificate of registration, the Applicant will be approved for the region for which it had the highest aggregate infrastructure score, and the second highest scored Applicant will be approved for the other region(s).

22. Rule 64-4.004 sets forth the circumstances under which dispensing organization approval will be revoked. Rule 64-4.005 details dispensing organization authorization and facility inspection procedures.

23. Pursuant to the provisions of Rule 64-4, Florida Administrative Code, Loop's Nursery timely submitted an application to the Department of Health on July 6, 2015 seeking authorization to serve as the Dispensing Organization in the Northeast Region. Loop's application was comparatively reviewed with four other competing applications seeking authorization to serve as the Dispensing Organization in the Northeast Region. The other four competing applications were filed by Chestnut Hill, San Felasco Nurseries, Bill's Nursery, and Hart's Plant Nursery.

24. On November 23, 2015, the Department issued its preliminary decision, in which it proposed to approve Chestnut Hill as the Dispensing Organization in the Northeast Region. Loop's Nursery was ranked as the next highest, qualified scored applicant. San Felasco's application was disqualified and not considered further. Specifically, in correspondence to San Felasco Nurseries, the Department notified San Felasco that its application failed to satisfy the required criminal background screening requirements set forth in the Rule. For this reason, the application of San Felasco was appropriately disqualified and should have never been scored. On December 11, 2015, San Felasco filed a petition for formal administrative hearing to contest OCU's decision

25. The Department's November 23, 2015 letter denying Loop's Nursery a license to cultivate low-THC cannabis was issued more than 90 days after the Department received Loop's Nursery's completed application. Section 120.60(1), Florida Statutes, states that, "An application for a license must be approved or denied within 90 days after receipt of a completed application unless a shorter period of time for agency action is provided by law." The Department previously acknowledged that it was processing applications pursuant to section

120.60, Florida Statutes. Accordingly, Loop's Nursery is entitled to a license under section 120.60(1), Florida Statutes.

NOTICE OF AGENCY DECISION

26. Loop's Nursery received notice of the Department's preliminary decision by letter dated November 23, 2015, which established a 21-day period for submission of a petition challenging the Department's preliminary decision pursuant to sections 120.569 and 120.57, Florida Statutes. This petition is timely filed.

PETITIONERS' SUBSTANTIAL INTERESTS

27. As an applicant to serve as the single authorized Dispensing Organization within the Northeast Region, Loop's Nursery is substantially adversely affected by the Department's preliminary decision to deny Loop's Nursery's application and to preliminarily approve the application filed by Chestnut Hill. Loop's Nursery has standing to seek a formal administrative hearing in this matter pursuant to sections 120.569 and 120.57(1), Florida Statutes.

DISPUTED ISSUES OF FACT

28. Disputed issues of material fact include but are not limited to:

- A. Whether Loop's Nursery's application to serve as the single approved Dispensing Organization in the Northeast Region satisfies all statutory and regulatory requirements for approval;
- B. Whether Loop's Nursery's application to serve as the single Dispensing Organization in the Northeast Region is, based on all applicable statutory and regulatory criteria, is superior to all other applications submitted for

authorization to serve as the single approved Dispensing Organization in the Northeast Region, including the application filed by Chestnut Hill;

- C. Whether the application filed by Chestnut Hill fails to satisfy the statutory and regulatory requirements for approval;
- D. Whether the application filed by Chestnut Hill should be denied for failure to satisfy the statutory and regulatory requirements for approval;
- E. Whether the application filed by Chestnut Hill is materially inferior to the application filed by Loop's Nursery;
- F. Whether the application filed by San Felasco fails to satisfy the statutory and regulatory requirements for approval;
- G. Whether the application filed by San Felasco should be denied for failure to satisfy the statutory and regulatory requirements for approval;
- H. Whether the application filed by San Felasco is materially inferior to the application filed by Loop's Nursery;
- I. Whether the application filed by Loop's Nursery to serve as the single Dispensing Organization in the Northeast Region should be approved;
- J. Whether the scoring of Loop's Nursery Application was arbitrary and capricious; and
- K. Disputed issues of fact raised and listed by other applicants in a formal administrative proceeding seeking the award of a low-THC Dispensing Organization Approval in the Northeast Region, assuming that all timely legal challenges in the Northeast Region are consolidated.

ULTIMATE FACTS INCLUDING FACTS WARRANTING

REVERSAL OF THE DEPARTMENT'S ACTION AS TO LOOP'S NURSERY

29. Loop's Nursery alleges that the following ultimate facts are true and warrant approval of Loop's Nursery's application and denial of the application filed by Chestnut Hill:

- A. Loop's Nursery's application to serve as the single approved Dispensing Organization in the Northeast Region satisfies all statutory and regulatory requirements for approval;
- B. Loop's Nursery's application to serve as the single Dispensing Organization in the Northeast Region is, based on all applicable statutory and regulatory criteria, superior to all other applications submitted for authorization to serve as the single approved Dispensing Organization in the Northeast Region, including the application filed by Chestnut Hill;
- C. Loop's Nursery's application is best able to further the statutory objective of ensuring accessibility and availability of low-THC cannabis to patients.
- D. The application filed by Chestnut Hill fails to satisfy the statutory and regulatory requirements for approval;
- E. The application filed by Chestnut Hill should be denied for failure to satisfy the statutory and regulatory requirements for approval;
- F. The application filed by Chestnut Hill is materially inferior to the application filed by Loop's Nursery;
- G. The application filed by San Felasco fails to satisfy the statutory and regulatory requirements for approval;
- H. The application filed by San Felasco should be denied for failure to satisfy the statutory and regulatory requirements for approval;

- I. The application filed by San Felasco is materially inferior to the application filed by Loop's Nursery;
- J. The application filed by Loop's Nursery to serve as the single Dispensing Organization in the Northeast Region should be approved;
- K. The scoring of Loop's Nursery Application was arbitrary and capricious; and
- L. The failure of the Department to approve or deny Loop's application within 90 days of receipt of Loop's completed application should result in Loop's application being deemed approved statutorily.

STATEMENT OF RULES AND STATUTES REQUIRING REVERSAL
OR MODIFICATION OF THE DEPARTMENT'S PROPOSED ACTION

30. Loop's Nursery is entitled to relief pursuant to sections 381.986, 120.569, and 120.57(1), Florida Statutes, and Chapter 64-4, Florida Administrative Code. Loop's Nursery's application to serve as the single Dispensing Organization in the Northeast Region is superior to the application filed by Chestnut Hill and all other applicants, and best satisfies all applicable statutory and regulatory criteria for approval and should be approved. The application filed by Chestnut Hill is materially deficient and fails to satisfy the statutory and regulatory criteria for approval and must be denied.

31. Loop's Nursery reserves the right to amend this Petition should additional reasons for legal challenge be uncovered during discovery or otherwise. Loop's Nursery has pending public records request of the Department for which the Department has not yet provided all responsive documents.

REQUEST FOR RELIEF

WHEREFORE, Loop's Nursery and Greenhouses, Inc. requests that the Department:

- A. Forward this matter to the Division of Administrative Hearings for assignment of an Administrative Law Judge to conduct a formal administrative hearing;
- B. Enter a final order approving Loop's Nursery's application to serve as the Dispensing Organization in the Northeast Region; and
- C. Grant such other relief as may be deemed just and proper.

DATED this 14th day of December 2015.

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By: 

**COUNSEL FOR PETITIONER LOOP'S NURSERY
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CERTIFICATE OF SERVICE

I hereby certify that the original of this Petition for Formal Administrative Hearing was filed with the Clerk of the Department of Health by hand delivery on December 14, 2015, and a true and correct copy served on December 14, 2015 by email transmission to the following:

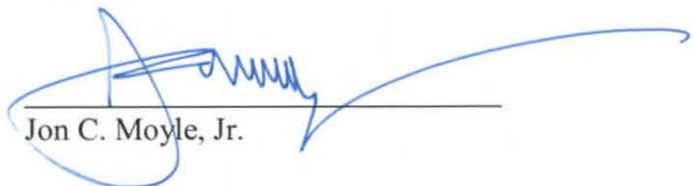
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