

**STATE OF FLORIDA
DEPARTMENT OF HEALTH**

16 APR 25 PM 1:47

OFFICE OF THE CLERK

LOOP'S NURSERY & GREENHOUSES,
INC.,

Petitioner,

Case No. 16-_____

v.

STATE OF FLORIDA, DEPARTMENT OF
HEALTH, OFFICE OF COMPASSIONATE USE;
and SAN FELASCO NURSERIES, INC., d/b/a
GRANDIFLORA,

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 April 4, 2016 agency action by the Florida Department of Health, Office of Compassionate use (the "Department" or "OCU") stating the Department of Health's intent to approve San Felasco Nurseries, Inc. d/b/a Grandiflora as a Dispensing Organization in the Northeast Region and in support thereof states as follows:

PRELIMINARY STATEMENT

1. The Florida Legislature adopted the Compassionate Use Medical Cannabis Act of 2014 (Chapter 2014-157 Laws of Florida) on May 2, 2014 (the "2014 Act"), for the purpose of providing statewide access to low-THC cannabis to patients suffering from diseases such as cancer and intractable epilepsy. Governor Rick Scott signed the 2014 Act into law on June 16, 2014, with an effective date of June 16, 2014.

2. Through the 2014 Act, the Legislature directed the Department to authorize, by January 1, 2015, the establishment of Dispensing Organizations, one in each of five regions throughout the state, to provide affected Floridians with access to low-THC cannabis, and to adopt rules to implement the 2014 Act. The Act sets forth specific criteria that an applicant seeking approval as a Dispensing Organization must satisfy to obtain approval. See, section 381.986(5)(b)1-7, Florida Statutes (2015).

3. The Department engaged in rulemaking on June 18, 2014 to implement the 2014 Act and published its proposed rules on August 14, 2014. The validity of the Department's proposed rules were challenged on September 29, 2014, in DOAH Consolidated Case No. 14-4296RP. On November 14, 2014 the Division of Administrative Hearings ("DOAH") issued a final order in Consolidated Case No. 14-4296RP, determining that the Department's proposed rules were an invalid exercise of delegated legislative authority.

4. The Department published revised proposed rules on February 6, 2015. Portions of the Department's proposed revised rules were challenged as an invalid exercise of delegated legislative authority, but on May 27, 2015 DOAH issued a final order determining that the challenged provisions were not invalid exercises of delegated legislative authority. The Department's revised proposed rules were adopted, and became effective on June 17, 2015 as Chapter 64-4, Florida Administrative Code.

5. Pursuant to the provisions of Chapter 64-4, Florida Administrative Code, the Department sought applications from prospective dispensing organizations and established an application filing deadline of 5:00 p.m. on July 8, 2015. Loop's Nursery timely submitted an application to the Department of Health on July 6, 2015 seeking authorization to serve as a 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 Tree Farms, LLC; San Felasco Nurseries, Inc.; Bill's Nursery; and Hart's Plant Nursery.

6. On November 23, 2015, the Department issued notice of its preliminary approval of Chestnut Hill's application. Loop's filed a petition for formal administrative proceeding challenging the Department's preliminary agency action, on December 14, 2015. San Felasco filed a petition challenging the Department's preliminary action, on December 11, 2015. Loop's petition was forwarded to DOAH and assigned DOAH Case No. 15-7274. Loop's case was later consolidated with DOAH Case No. 15-7268 initiated by San Felasco and with DOAH Case No. 15-7276, a cross-petition initiated by Chestnut Hill. The final hearing in DOAH Consolidated Case No. 15-7268 is scheduled to commence July 5, 2016.

7. During the 2016 legislative session, the Legislature adopted Chapter 2016-123, Laws of Florida, which substantially amended portions of section 381.986, Florida Statutes, and added numerous additional provisions to the statute. Chapter 2016-123, Laws of Florida was signed into law by the Governor on March 25, 2016 with an effective date of March 25, 2016 (the "2016 Act").

8. The 2016 Act leaves intact the Legislative directive to the Department to authorize the establishment of Dispensing Organizations, one in each of five regions throughout the state, based on the criteria set forth in section 381.986(5)(b)1-7, Florida Statutes, but eliminates the requirement that such Dispensing Organizations be authorized by January 1, 2015. Specifically, section 381.986(5)(b) of the 2016 Act provides:

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

(a) Create and maintain a secure, electronic, and online compassionate use registry for the registration of physicians, ~~and patients, and the legal representatives of patients~~ as provided under this section. The registry must be accessible to law enforcement agencies and to a dispensing organization ~~in order~~ to verify the authorization of a patient or a patient's legal representative to possess patient authorization for low-THC cannabis, medical cannabis, or a cannabis delivery device and record the low-THC cannabis, medical cannabis, or cannabis delivery device 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, medical cannabis, or a cannabis delivery device 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 performance bond. However, upon a dispensing organization's serving at least 1,000 qualified

patients, the dispensing organization is only required to maintain a \$2 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.

9. The 2016 Act thus leaves intact the statutory basis for the administrative proceedings pending in DOAH Consolidated Case No. 15-7268, including Loop's challenge to the Department's preliminary denial of Loop's application to serve as a Dispensing Organization in the Northeast Region pending in DOAH Case No. 15-7274.

10. In addition, the Act establishes additional pathways to approval of an applicant seeking authorization to serve as a Dispensing Organization. Specifically, Section 3 of the Act provides:

Section 3. (1) Notwithstanding s. 381.986(5)(b), Florida Statutes, a dispensing organization that receives notice from the Department of Health that it is approved as a region's dispensing organization, posts a \$5 million performance bond in compliance with rule 64-4.002(5)(e), Florida Administrative Code, meets the requirements of and requests cultivation authorization pursuant to rule 64-4.005(2), Florida Administrative Code, and expends at least \$100,000 to fulfill its legal obligations as a dispensing organization; or any applicant that received the highest aggregate score through the department's evaluation process, notwithstanding any prior determination by the department that the applicant failed to meet the requirements of s. 381.986, Florida Statutes, must be granted cultivation authorization by the department and is approved to operate as a dispensing organization for the full term of its original approval and all subsequent renewals pursuant to s.381.986, Florida Statutes. Any applicant that qualifies under this subsection which has not previously been approved as a dispensing organization by the department must be given approval as a dispensing organization by the department within 10 days after the effective date of this act, and within 10 days after receiving such approval must comply with the bond requirement in rule 64-4.002(5)(e), Florida Administrative Code,

and must comply with all other applicable requirements of chapter 64-4, Florida Administrative Code.

(2) If an organization that does not meet the criteria of subsection (1) receives a final determination from the Division of Administrative Hearings, the Department of Health, or a court of competent jurisdiction that it was entitled to be a dispensing organization under s. 381.986, Florida Statutes, and applicable rules, such organization and an organization that meets the criteria of subsection (1) shall both be dispensing organizations in the same region. During the operations of any dispensing organization that meets the criteria in this section, the Department of Health may enforce rule 64-4.005, Florida Administrative Code, as filed on June 17, 2015.

(3) This section does not apply to s. 381.986 (5)(c), Florida Statutes.

11. On April 4, 2016, the Department issued notice of its intent to approve San Felasco's pending application to serve as a Dispensing Organization in the Northeast Region, "pursuant to chapter 2016-123, § 3, Laws of Florida." A copy of the Department's April 4, 2016 preliminary agency action is attached hereto as Attachment "A."

12. The Department's preliminary approval of San Felasco is contingent upon the factual determination that San Felasco satisfies the statutory requirements set forth in section 3 of the 2016 Act. The Act does not contain any legislative findings pertaining to San Felasco's satisfaction of any of the criteria set forth in the Act. To the extent San Felasco seeks approval as a Dispensing Organization pursuant to §3 of Chapter 2016-123, Laws of Florida, San Felasco is required to demonstrate compliance with the criteria for approval set forth in §3 of Chapter 2016-123, Laws of Florida and chapter 64-4, Florida Administrative Code.

PARTIES

13. Petitioner Loop's 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 application to serve as a dispensing organization, submitted pursuant to section 381.986(b), Florida Statutes

(2015), satisfies all statutory and regulatory criteria for approval as a Dispensing Organization. Loop's application remains pending in Consolidated DOAH Case No. 15-7268.

14. Respondent Department of Health is the state agency authorized to approve dispensing organizations pursuant to section 381.986, Florida Statutes, and Chapter 2016-123, Laws of Florida. Respondent's mailing address is 2585 Merchants Row Blvd., Tallahassee, Florida, 32399.

15. Respondent San Felasco is a Florida for-profit corporation with its principal place of business at 7315 Northwest 126th Street, Gainesville, Florida, 32653.

NOTICE OF AGENCY DECISION

16. Loop's obtained notice of the Department's preliminary action from the Department's website, on or about April 4, 2016. This petition is timely filed.

LOOP'S SUBSTANTIAL INTERESTS

17. The Department's April 4, 2016 preliminary agency action is based on the application filed by San Felasco to serve as a Dispensing Organization in the Northeast Region, which was comparatively reviewed against the application filed by Loop's. Loop's is substantially adversely affected by the Department's April 4, 2016 preliminary agency action to the extent that such action adversely affects Loop's entitlement to a formal administrative hearing on its own application and to comparative review against San Felasco's application, and to the extent that the Department's April 4, 2016 preliminary agency action adversely affects Loop's entitlement to final approval as a Dispensing Organization in the Northeast Region. In addition, because the Department's April 4, 2016 preliminary action does not specify the statutory or regulatory basis for the Department's April 4, 2016 preliminary approval of San Felasco's pending application, other than the Department's general reference to "chapter 2016-123, § 3,

Laws of Florida,” the Department’s April 4, 2015 preliminary agency action adversely affects Loop’s substantial interests to the extent the Department’s April 4, 2016 preliminary agency action, if final, would preclude Loop’s from seeking approval as a Dispensing Organization pursuant to the provisions of chapter 2016-123, § 3, Laws of Florida.

DISPUTED ISSUES OF FACT

18. Disputed issues of material fact include but are not limited to:
 - A. Whether Loop’s Nursery’s pending application to serve as a Dispensing Organization in the Northeast Region satisfies all statutory and regulatory requirements for approval, pursuant to the provisions of section 381.986(5)b and applicable rule criteria;
 - B. Whether Loop’s Nursery’s application to serve as a Dispensing Organization in the Northeast Region is superior to all other pending applications submitted for authorization to serve as a Dispensing Organization in the Northeast Region, including the application filed by San Felasco;
 - C. Whether the pending application filed by San Felasco fails to satisfy the statutory and regulatory requirements for approval pursuant to the provisions of section 381.986(5)b and applicable rule criteria;
 - D. Whether the pending application filed by San Felasco is materially inferior to the application filed by Loop’s Nursery;
 - E. Whether San Felasco fails to satisfy the statutory requirements for approval as a Dispensing Organization set forth in §3 of Chapter 2016-123, Laws of Florida;

- F. Whether Loop's application satisfies the statutory requirements for approval as a Dispensing Organization as set forth in section 3 of Chapter 2016-123, Laws of Florida;
- G. Whether San Felasco fails to satisfy the criteria for approval set forth in chapter 64-4, Florida Administrative Code.
- H. Whether Loop's application satisfies the criteria for approval set forth in chapter 64-4, Florida Administrative Code.
- I. Whether San Felasco fails to satisfy the criteria for approval as a Dispensing Organization set forth in section 381.986, Florida Statutes;
- J. Whether the Department's April 4, 2016 preliminary agency action violates section 381.986, Florida Statutes;
- K. Whether the Department's April 4, 2016 preliminary agency action violates the provisions of Chapter 2016-123, Laws of Florida.

ULTIMATE FACTS INCLUDING FACTS WARRANTING REVERSAL OR MODIFICATION OF THE DEPARTMENT'S ACTION

19. Loop's alleges that the following ultimate facts warrant reversal or modification of the Department's April 4, 2016 preliminary agency action:

- A. Loop's Nursery's pending application to serve as a Dispensing Organization in the Northeast Region satisfies all statutory and regulatory requirements for approval, pursuant to the provisions of section 381.986(5)b and applicable rule criteria;
- B. Loop's Nursery's application to serve as a Dispensing Organization in the Northeast Region is superior to all other pending applications submitted

for authorization to serve as a Dispensing Organization in the Northeast Region, including the application filed by San Felasco;

- C. The pending application filed by San Felasco fails to satisfy the statutory and regulatory requirements for approval pursuant to the provisions of section 381.986(5)b and applicable rule criteria;
- D. The pending application filed by San Felasco is materially inferior to the application filed by Loop's Nursery;
- E. San Felasco fails to satisfy the statutory requirements for approval as a Dispensing Organization set forth in §3 of Chapter 2016-123, Laws of Florida;
- F. Loop's application satisfies the statutory requirements for approval as a Dispensing Organization as set forth in section 3 of Chapter 2016-123, Laws of Florida;
- G. San Felasco fails to satisfy the criteria for approval set forth in chapter 64-4, Florida Administrative Code.
- H. Loop's application satisfies the criteria for approval set forth in chapter 64-4, Florida Administrative Code.
- I. San Felasco fails to satisfy the criteria for approval as a Dispensing Organization set forth in section 381.986, Florida Statutes;
- J. The Department's April 4, 2016 preliminary agency action violates section 381.986, Florida Statutes;
- K. The Department's April 4, 2016 preliminary agency action violates the provisions of Chapter 2016-123, Laws of Florida.

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

20. Loop's Nursery is entitled to relief pursuant to sections 381.986, 120.569, and 120.57(1), Florida Statutes, Chapter 2016-123, Laws of Florida, and Chapter 64-4, Florida Administrative Code.

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 denying approval to San Felasco to serve as a Dispensing Organization in the Northeast Region;
- C. Enter a final order approving Loop's to serve as a Dispensing Organization in the Northeast Region; and
- D. Grant such other relief as may be deemed just and proper.

DATED this 25th day of April 2016.

Jon C. Moyle Jr.
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Fla. Bar No. 0037745
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By: /s/ Jon C. Moyle
**COUNSEL FOR PETITIONER LOOP'S
NURSERY & AND GREENHOUSES, INC.**

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 April 25th, 2016, and a true and correct copy served on interested parties on April 25th, 2016 by email transmission to the following:

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/s/ Jon C. Moyle
Jon C. Moyle, Jr.

Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



Rick Scott
Governor

Celeste Philip, MD, MPH
Interim State Surgeon General

Vision: To be the Healthiest State in the Nation

April 4, 2016

San Felasco Nurseries, Inc., d/b/a/ Grandiflora
7315 NW 126th Street
Gainesville, Florida 32653

Re: Low-THC Cannabis Dispensing Organization Application

Dear Applicant:

I am pleased to inform you that San Felasco Nurseries, Inc., d/b/a/ Grandiflora (San Felasco) is approved as a dispensing organization for the Northeast region of Florida, pursuant to chapter 2016-123, § 3, Laws of Florida.

San Felasco has 10 business days to post a \$5 million performance bond in accordance with Rule 64-4.002(5)(e), of the Florida Administrative Code. The original bond, payable to the Florida Department of Health, must be received by the Department no later than 5:00 PM EST on April 18, 2016. If the performance bond is canceled and San Felasco fails to file a new bond with the Department in the required amount on or before the effective date of cancellation, San Felasco's approval shall be revoked.

San Felasco must notify the Department that it is prepared to be inspected and seek authorization to begin cultivation, processing, and dispensing. The following deadlines, as outlined in Rule 64-4.005, of the Florida Administrative Code, apply.

Cultivation

San Felasco has 75 days from this approval to request Cultivation Authorization. No less than 30 calendar days prior to the initial cultivation of cannabis San Felasco shall notify the Department that it is ready to begin cultivation, is in compliance with Section 381.986, F.S., and Chapter 64-4, of the Florida Administrative Code, and is seeking Cultivation Authorization. Failure to meet the deadline to seek Cultivation Authority may result in the revocation of the Department's approval. Please note, no cannabis plant source material may be present in any Dispensing Organization facility prior to Cultivation Authorization.

Processing

No less than 10 calendar days prior to the initial processing of cannabis, San Felasco must notify the Department that it is ready to begin processing, is in compliance with Section 381.986, F.S., and Chapter 64-4, of the Florida Administrative Code, and is seeking Processing Authorization.

Florida Department of Health

Office of Compassionate Use
4052 Bald Cypress Way, Bin A-06 • Tallahassee, FL 32399-1703
PHONE: (850) 245-4444 • FAX (850) 245-4748

ATTACHMENT "A"

www.FloridaHealth.gov

TWITTER: HealthyFLA
FACEBOOK: FLDepartmentofHealth
YOUTUBE: fldoh
FLICKR: HealthyFla
PINTEREST: HealthyFla


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Dispensing

San Felasco must begin dispensing derivative product within 210 calendar days of being granted cultivation authorization. No less than 10 calendar days prior to the initial dispensing of derivative product, San Felasco must notify the Department that it is ready to begin dispensing, is in compliance with Section 381.986, F.S., and Chapter 64-4, of the Florida Administrative Code, and is seeking Dispensing Authorization. Failure to meet the deadline to begin dispensing may result in the revocation of the Department's approval.

Finally, submission of an application for Dispensing Organization approval constitutes permission for entry by the Department at any reasonable time, into any Dispensing Organization facility to inspect any portion of the facility; review the records required pursuant to Section 381.986, F.S., or Chapter 64-4, of the Florida Administrative Code; and identify samples of any cannabis or Derivative Product for laboratory analysis, the results of which shall be forwarded to the Department.

Once again, congratulations on receiving approval to become a dispensing organization for the Northeast region. Should you have any questions about this approval, please contact the Florida Department of Health, Office of Compassionate Use.

Sincerely,


AL 6/17
Anna Likos, MD, MPH
Acting Deputy Secretary for Health

CB/cc
cc: Office of the General Counsel

NOTICE OF RIGHTS

This notice is agency action for purposes of section 120.569, Florida Statutes. A party whose substantial interest is affected by this action may petition for an administrative hearing pursuant to sections 120.569 and 120.57, Florida Statutes. A petition must be filed in writing and must be received by the Agency Clerk within twenty-one (21) days from receipt of this notice. The petition may be mailed to the Agency Clerk, Department of Health, 4052 Bald Cypress Way, BIN #A-02, Tallahassee, FL 32399-1703; hand delivered to the Agency Clerk, Department of Health, 2585 Merchants Row Blvd., Prather Building, Suite 110, Tallahassee, FL; or sent by facsimile to (850) 413-8743. Such petition must be filed in conformance with Florida Administrative Code Rules 28-106.201 or 28-106.301, as applicable.

Mediation is not available.

Failure to file a petition within 21 days shall constitute a waiver of the right to a hearing on this agency action.