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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **GEORGE L. MEE MEMORIAL HOSPITAL** **300 Canal Street** **King City, CA 93930** **Applicant for Sterile Compounding Permit** Respondent.	Case No. 6807 **WITHDRAWAL OF STATEMENT OF ISSUES**

On January 28, 2021, Respondent George L. Mee Memorial Hospital withdrew its appeal and request for a hearing in the denial of its application for a Sterile Compounding Permit issued by the Board of Pharmacy. Accordingly, Statement of Issues No. 6807, filed against Respondent, is withdrawn without prejudice, and the denial of Respondent's application is affirmed. The earliest date on which Respondent may reapply for a Sterile Compounding Permit is one year after the effective date of the denial. That effective date is the issue date of this Withdrawal of Statement of Issues.

DATED: 2/17/2021

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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In the Matter of the Statement of Issues Against**:**	Case No. 6807
GEORGE L. MEE MEMORIAL HOSPITAL **300 Canal Street** **King City, CA 93930** **Applicant for Sterile Compounding Permit** Respondent.	**STATEMENT OF ISSUES**

PARTIES

1. Anne Sodergren (Complainant) brings this Statement of Issues solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.

2. On or about August 29, 2017, the Board received an application for a sterile compounding permit from George L. Mee Memorial Hospital (Respondent). On or about September 17, 2017, Keith A. Bradkowski, Chief Nursing Officer for Respondent, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. On or about October 22, 2018, the Board received an amended application from Respondent. On or about October 18, 2018, Keith A. Bradkowski, Chief Nursing Officer for Respondent, certified under penalty of perjury to the truthfulness of all statements, answers, and

representations in the amended application. The Board denied the application on August 30, 2019.

JURISDICTION

3. This Statement of Issues is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances Act [Health & Safety Code, § 11000 et seq.].

STATUTORY AND REGULATORY PROVISIONS

Business and Professions Code:

5. Code section 480 states, in pertinent part:

> (a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:
>
> . . .
>
> (3)(A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.
>
> . . .

6. Code section 4300(c) states that the Board may refuse a license to any applicant guilty of unprofessional conduct.

7. Code section 4301 states, in pertinent part:

> The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:
>
> . . .
>
> (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.
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> . . .

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8. Code section 4302 states:

The board may deny, suspend, or revoke any license where conditions exist in relation to any person holding 10 percent or more of the ownership interest or where conditions exist in relation to any officer, director, or other person with management or control of the license that would constitute grounds for disciplinary action against a licensee.

9. Code section 4306 states:

It shall constitute unprofessional conduct and a violation of this chapter for any person licensed under this chapter to violate, attempt to violate, directly or indirectly, or assist in or abet the violation of, or conspire to violate, any provision or term of this article, the Moscone-Knox Professional Corporation Act, or any regulations duly adopted under those laws.

California Code of Regulations:

10. California Code of Regulations, title 16, section 1735.2(j), states:

Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

11. California Code of Regulations, title 16, section 1735.5, states:

. . .

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

. . .

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12. California Code of Regulations, title 16, section 1735.7(c), states:

Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.

13. California Code of Regulations, title 16, section 1735.8(c), states:

The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.

14. California Code of Regulations, title 16, section 1751.4, states, in pertinent part:

(a) No sterile injectable product shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.

. . .

(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.

15. California Code of Regulations, title 16, section 1751.7, states, in pertinent part:

(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-chart to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:

. . .

(4) Written justification of the chosen expiration dates for compounded sterile injectable products.

. . .

PRIOR LICENSURE

16. On or about May 20, 2014, the Board issued Sterile Compounding Permit No. LSC 100083 to Respondent. The License was in full force and effect at all times relevant to the charges brought herein. The License expired on February 1, 2017. From November 23, 2016 until November 15, 2017, Fred Raleigh, RPH 27362, was the Pharmacist in Charge.

CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

17. Respondent's application is subject to denial under Code sections 480(3)(A), 4300(c), 4301(o), 4302 and 4306 in that Respondent committed acts of unprofessional conduct by violating laws pertaining to pharmacy practice that, if committed by a licensee, would be grounds for license suspension or revocation, as follows:

a. Failure to Complete Compounding Self-Assessment:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1735.2(j), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that the Pharmacy Board's inspector found during an inspection at Respondent Hospital on or about December 20, 2016, that the compounding self-assessment form had not been completed.

b. Failure to Perform End Product and Sterility Testing:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1735.8(c), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent failed to enact and implement a quality assurance plan requiring end product testing for potency and sterility. On or about December 20, 2016, during an inspection at Respondent Hospital, the Pharmacy Board's inspector found Respondents had not done end product testing on a compounded product for sterility or potency during the preceding year.

c. Failure to Require Compounding Staff to Demonstrate Knowledge:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1735.7(c), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent failed to require pharmacy personnel to demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug

preparation. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found Respondent had hired pharmacists and had allowed the new pharmacists to compound without first performing gloved fingertip and media fill tests. Pharmacist in Charge Fred Raleigh compounded sterile injectable products and had not performed an annual gloved fingertip and media fill test.

d. Failure to Perform Annual Review of Compounding Policies and Procedures:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1735.5(b), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent failed to perform, and document on an annual basis, the performance by the pharmacist-in-charge of a review of policies and procedures. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found that the pharmacist-in-charge had not reviewed the compounding policies and procedures during the preceding year.

e. Lack of Procedure to Advise of Changes to Compounding Policies and Procedures:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1735.5(c)(1), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent failed to have any procedure for notifying staff assigned to compounding duties of any changes in policies or procedures. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found that the facility had no policy or procedure stating how staff were to be notified of new or changed compounding policies and procedures.

f. Unlawful Operation:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1751.4(a), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent allowed and/or engaged in sterile drug preparation and

compounding when Respondent knew, or should have known, that the compounding environment failed to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found that the compounding room was a converted patient room with a full bathroom, openable windows, no line of demarcation, and a crowded, disorganized segregated clean room.

g. Inadequate Cleaning of Facility:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1751.4(d), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent failed to clean the facility in the manner required by law. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found that the compounding room's ceilings, walls, floors, shelves, tables and stools had not been cleaned weekly since the last week in April 2016.

h. Inappropriate Beyond-Use Dates:

Respondent violated section 4301(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16, section 1751.7(a)(4), by directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or regulations governing the practice of pharmacy, in that Respondent utilized inappropriate beyond use dates for compounded sterile drug preparations. On or about December 20, 2016, during an inspection at Respondent pharmacy, the Pharmacy Board's inspector found that the facility should have a beyond-use date of no more than an hour, or immediate use. Beyond use dates assigned to sterile injectable drugs were: 12 hour, 24 hours, and longer per compounding records and master formulas.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Denying the application of George L. Mee Memorial Hospital for a sterile compounding permit; and

2. Taking such other and further action as deemed necessary and proper.

DATED: September 26, 2019

ANNE SODERGREN
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant