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

In the Matter of the Accusation Against: **SAN DIEGO OPTIMUM COMPOUNDING, INC. dba SAN DIEGO OPTIMUM COMPOUNDING, MAII EL-SHATANOUFY, CEO** **12265 Scripps Poway Parkway, Suite 114** **Poway, CA 92064** **Pharmacy Permit No. PHY 53633** **Sterile Compounding Permit No. LSC 100831** **MAII EL-SHATANOUFY** **15054 Almond Orchard Lane** **San Diego, CA 92131** **Pharmacist License No. RPH 63672** Respondents.	Case No. 7228 **FIRST AMENDED ACCUSATION**
In the Matter of the Statement of Issues Against: **SAN DIEGO OPTIMUM COMPOUNDING, INC. dba SAN DIEGO OPTIMUM COMPOUNDING** **Renewal of Sterile Compounding Permit** Respondent.	Case No. 7383 **STATEMENT OF ISSUES**

PARTIES

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

2. On or about October 15, 2015, the Board of Pharmacy issued Pharmacy Permit Number PHY 53633 to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding (Respondent San Diego Optimum). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2023.

3. On or about December 2, 2015, the Board of Pharmacy issued Sterile Compounding Permit Number LSC 100831 to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding (Respondent San Diego Optimum). The Sterile Compounding Permit was in full force and effect at all times relevant to the charges brought herein and expired on October 1, 2022, and was not renewed.

4. On or about September 20, 2022, the Board denied the renewal of the Sterile Compounding Permit Number LSC 100831 issued to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding.

5. On or about February 9, 2010, the Board of Pharmacy issued Pharmacist License Number RPH 63672 to Maii El-Shatanoufy (Respondent El-Shatanoufy). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2024. Respondent El-Shatanoufy has served and been listed in Board records as Pharmacist-in-Charge (PIC) of Respondent San Diego Optimum from October 15, 2015.

JURISDICTION

6. The First Amended Accusation and Statements of Issues are brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

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7. 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*.).

8. Code section 4300, subdivision (a) provides that every license issued by the Board may be suspended or revoked.

9. Code section 4300, subdivision (c) states:

> The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. . .

10. Code section 4300.1 states:

> The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

11. Code section 4307 states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:
>
> (1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.
>
> (2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.
>
> (b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

INTRODUCTION

12. This case is about the compounding of prescription drugs, including those designated for sterile administration, in a pharmacy. Pharmacy compounding is when a licensed pharmacist combines, mixes, or alters drug ingredients to create a medication tailored to the needs of an individual patient. (e.g., Cal. Code Regs., tit. 16, § 1735.) Compounding is a form of drug manufacturing subject to the drug manufacturing requirements of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 301 et seq.]. Compounding in a pharmacy as a form of drug manufacturing is permitted under federal law by section 503A of the FDCA [21 U.S.C. § 353a].

13. Compounds may be either "non-sterile" or "sterile," depending on the intended route of drug administration. Sterile drugs are those intended for parenteral administration (i.e., other than through the digestive system), including injectables and ophthalmic or inhalation drugs in aqueous format. It is important that these drugs be sterile and uncontaminated, because they bypass some of the body's natural defenses against pathogens and impurities.

14. California law allows all licensed pharmacists to compound non-sterile drug products in licensed pharmacies. (e.g., Bus. & Prof. Code, §§ 4037, 4051, 4110.) All compounding must be consistent with standards in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP-NF), including relevant testing and quality assurance standards. (Bus. & Prof. Code, § 4126.8.) The Pharmacy Law also contains additional standards that supplement the USP-NF standards. (Id.; see, e.g., Bus. & Prof. Code, §§ 4126.10, 4127 et seq., 4128 et seq., 4129 et seq., Cal. Code Regs., tit. 16, §§ 1735 et seq., 1751 et seq.)

15. An additional specialty license is required before any licensed pharmacy is allowed to compound sterile drug products. (Bus. & Prof. Code, § 4127 et seq.) And particular

regulatory requirements apply to preparation, maintenance, and distribution of sterile drug products. (Cal. Code Regs., tit. 16, § 1751 et seq.; see also Cal. Code Regs., tit. 16, § 1735 et seq.) Each sterile compounding pharmacy must be inspected prior to each annual renewal of a sterile compounding license to ensure compliance with all compounding and sterile compounding requirements. (Bus. & Prof. Code, § 4127.1, subd. (c).) All of this demonstrates the attention and resources devoted to sterile drug compounding. This is because of the unique risks posed by sterile drug products. In 2012, for instance, a contaminated sterile drug compound was widely distributed, and caused a nationwide fungal meningitis outbreak, killing 64 people and causing infections in almost 800 others who received the drug.

16. In this case, Respondent engaged in a number of sterile and nonsterile compounding violations. These violations were found during the inspections on July 31, 2020, September 11, 2020, September 20, 2021, February 28, 2022, and September 12, 2022. These violations include failure to comply with compounding standards, failure to comply with pharmacy policy and procedures, failure to keep required compounding logs, failure to correctly label sterile compounds, along with many other violations. Furthermore, Respondents incorrectly compounded Amlodipine, which resulted in the death of a dog.

STATUTORY PROVISIONS

17. Code section 4059 states:

> (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

18. Code section 4081 states:

> (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187 , clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code

who maintains a stock of dangerous drugs or dangerous devices.

19. Code section 4110 states:

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

…

20. Code section 4113 states:

(c) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

21. Code section 4127.2 states:

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually pursuant to subdivision (v) of Section 4400.

22. Code section 4126.8 states:

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding

23. Code section 4163 states:

(a) A manufacturer, wholesaler, repackager, or pharmacy shall not furnish a

…

24. Code section 4300 states:

…

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the

following:

(1) Medical or psychiatric evaluation.

(2) Continuing medical or psychiatric treatment.

(3) Restriction of type or circumstances of practice.

(4) Continuing participation in a board-approved rehabilitation program.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

(7) Compliance with laws and regulations governing the practice of pharmacy.

25. Code section 4301 states:

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 includes, but is not limited to, any of the following:

…

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(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.

…

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

…

26. Code section 4306.5 states:

Unprofessional conduct for a pharmacist may include any of the following:

(a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the

ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.

…

REGULATORY PROVISIONS

27. California Code of Regulations, title 16, section 1716 states:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-accepted pharmaceutical practice in the compounding or dispensing of a prescription.

28. California Code of Regulations, title 16, section 1735.2 states:

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

…

(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following

elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

…

(i) Every compounded drug preparation shall be given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:

(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,

(B) the chemical stability of any one ingredient in the compounded drug preparation,

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision; and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:

(i) the nature of the drug and its degradation mechanism,

(ii) the dosage form and its components,

(iii) the potential for microbial proliferation in the preparation,

(iv) the container in which it is packaged,

(v) the expected storage conditions, and

(vi) the intended duration of therapy.

Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subdivision may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

29. California Code of Regulations, title 16, section 1735.3, subdivision (a) states:

(a) For each compounded drug preparation, pharmacy records shall include:

(1) The master formula document.

(2) A compounding log consisting of a single document containing all of the

following:

(A) Name and Strength of the compounded drug preparation.

(B) The date the drug preparation was compounded.

(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.

(D) The identity of the pharmacist reviewing the final drug preparation.

(E) The quantity of each ingredient used in compounding the drug preparation.

(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile preparations compounded in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

(G) A pharmacy-assigned unique reference or lot number for the compounded drug preparation.

(H) The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format.

(I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

30. California Code of Regulations, title 16, section 1735.4, subdivision (a) states:

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV

solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

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

(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

…

(c) The policies and procedures shall include at least the following:

…

(3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

…

32. California Code of Regulations, title 16, section 1735.6 states:

…

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

…

(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3)

(A) For sterile compounding, each BSC or CACI shall be externally exhausted.

(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted. For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

33. California Code of Regulations, title 16, section 1735.7 states:

(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

34. California Code of Regulations, title 16, section 1735.8 states:

…

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

35. California Code of Regulations, title 16, section 1751.3, subdivision (a), states:

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable

surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

(9) Facility management including certification and maintenance of controlled environments and related equipment.

(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(11) Hand hygiene and garbing.

(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

(14) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(18) Proper use of equipment and supplies.

(19) Quality assurance program compliant with sections 1711, 1735.8 and

1751.7.

(20) Record keeping requirements.

(21) Temperature monitoring in compounding and controlled storage areas.

(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(23) Use of automated compounding devices (if applicable).

(24) Visual inspection and other final quality checks of sterile drug preparations.

36. California Code of Regulations, title 16, section 1751.4 states:

…

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

…

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.7.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

…

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

…

37. California Code of Regulations, title 16, section 1751.7 states:

…

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

…

(e)

(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

38. California Code of Regulations, title 16, section 1751.8, subdivision (a), states:

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia - National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

39. California Code of Regulations, title 16, section 1751.9 states:

…

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

40. California Code of Regulations, title 16, section 1761, subdivision (a), states:

No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.

COST RECOVERY

41. Section 125.3 of the Code provides, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

42. On or about June 22, 2020, the Board received a complaint from MS alleging that Respondents incorrectly compounded Amlodipine, which resulted in the death of MS's dog. Amlodipine is used to treat high blood pressure and is a dangerous drug under Code section 4022.

43. On or about June 16, 2020, Respondent received a prescription for "Amlodipine 1.25 mg tab, 1 tablet orally every 24 hours #60, 4 refills." Respondent spoke with the veterinarian and the prescription was changed to "2.5 mg/ml liquid, dive 0.5 ml orally every 24 hours, #30 + 4 refills." MS picked up the compound from Respondent on June 16, 2020.

44. On or about June 17, 2020, at approximately 9:00 a.m., MS gave the dog "Muffy" the first dose from the compounded Amlodipine. At 10:55 a.m., Muffy cried out and collapsed. Muffy was conscious but was not exhibiting "normal behavior." MS stated that it was like Muffy "was in a daze." MS took Muffy to the veterinarian right away. The veterinarian took an x-ray of Muffy's lungs and listened to her heart and told MS to take Muffy to an emergency (ER)

veterinarian. MS went to the emergency veterinarian immediately and on the drive there Muffy collapsed in MS's lap. The ER veterinarian stated that Muffy had extremely low blood pressure and started her on fluids to keep Muffy's pressure up. Muffy stayed at the hospital, and MS had hoped that she would be ok. However, when MS called the veterinarian later that day she was told Muffy's blood pressure dropped every time they backed off the fluids, but the fluids were overwhelming Muffy's kidneys. The veterinarian had contacted poison control and was told the half-life of Amlodipine was 70 hours.

45. On Thursday, June 18, 2020, the ER veterinarian called MS and asked if she wanted to continue treatment for Muffy. Muffy had "profound collapse" and her renal function was "way off the charts." MS requested the treatment continue because Muffy had been fine before being given the dose of Amlodipine. MS was hoping if the Amlodipine could get out of her system Muffy could recover. MS was very emotional and explained that by Friday, June 19, 2020, the decision was made to euthanize Muffy. All of Muffy's systems had shut down and the veterinarian told MS that Muffy was suffering.

46. MS sent the Amlodipine compound to the veterinary lab at UC Davis and the lab reported the concentration of Amlodipine was 160mg/ml, while the label on the Amlodipine was listed as 2.5 mg/ml. Based on the results of an independent California Animal Health and Food Safety (CAHFS) Laboratory, the Amlodipine suspension prepared for Muffy (RX #519037) contained 160mg/ml of Amlodipine instead of the 2.5mg/ml prescribed. An overexposure of the drug to this extent would likely correlate with the dramatic symptoms Muffy experienced immediately after receiving a dose of the drug, and ultimately her demise.

47. Based upon the complaint and the information concerning Muffy, an investigation was commenced and documents were requested from Respondents. In addition to other documents, Respondents provided a copy of the compounding records for the Amlodipine. The documents provided by Respondents established the following.

i. The master formula that did not include the quality review required at each step in the preparation of the Amlodipine 2.5 mg/ml aqueous suspension 30 ml.

ii. The NDC number and lot number for Amlodipine Besylate 10 mg tablets recorded on the compounding log did not match the NDC number and lot number noted on the Master Formula. The NDC number on the compounding log was not the NDC number on the bottle of Amlodipine 10 mg tablets and the lot number on the compounding log was the lot number for Amlodipine powder, not tablets.

iii. Documentation of training and competencies for RPH Sina Faton (RPH 76333) included one compounding competency demonstration on July 3, 2017. The other competency documentation for RPH Faton was her signature on a procedure for checking a compounded prescription. There was no documentation of on-going competency evaluations for all policies and procedures involved in compounding.

iv. Documentation of training and competencies for TCH Lily Negrete (TCH 115459) included three compounding personnel competency demonstrations in 2020. There was no documentation of training or on-going competency evaluations for all policies and procedures involved in compounding.

STERILE COMPOUNDING RENEWAL INSPECTION

48. On or about July 31, 2020, Board inspectors conducted a sterile compounding renewal inspection. Thereafter on or about September 11, 2020, September 20, 2021, and February 28, 2022, Board inspectors conducted follow-up inspections. On or about September 12, 2022, a Board inspector conducted an additional sterile compounding renewal inspection.

49. Following the inspections, Board issued Orders of Correction and Written Notices that included a number of violations of pharmacy law. These violations are listed in the Seventh through Thirty-Fifth causes for discipline, listed below.

FIRST CAUSE FOR DISCIPLINE

(Variation from Prescription Against All Respondents)

50. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1716, for deviating from the requirements of a prescription for dispensing Amlodipine 160 mg/ml instead of the prescribed 2.5 mg/ml, as set forth in paragraphs 42 through 47, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Failure to Comply with Regulations Against All Respondents)

51. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2 (e), for using a master formula that did not include the quality review required at each step in the preparation of the Amlodipine 2.5 mg/ml aqueous suspension 30 ml, as set forth in paragraphs 42 through 47, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Failure to Keep Accurate Record Keeping for Compounded Drugs Against All Respondents)

52. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.3, subdivision (a)(2), in that the NDC number and lot number for Amlodipine Besylate 10 mg tablets recorded on the compounding log did not match the NDC number and lot number noted on the Master Formula. The NDC number on the compounding log was not the NDC number on the bottle of Amlodipine 10 mg tablets and the lot number on the compounding log was the lot number for Amlodipine powder, not tablets, as set forth in paragraphs 42 through 47, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Train Compounding Staff Against All Respondents)

53. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.7, subdivision (a), section 1735.7, subdivision (b) and section 1735, subdivisions (c)(3) and (4), for failing to train compounding staff as follows:

i. Documentation of training and competencies for RPH Sina Faton (RPH 76333) included one compounding competency demonstration on July 3, 2017. The other competency documentation for RPH Faton was her signature on a procedure for checking a compounded

prescription. There was no documentation of on-going competency evaluations for all policies and procedures involved in compounding.

ii. Documentation of training and competencies for TCH Lily Negrete (TCH 115459) included three compounding personnel competency demonstrations in 2020. There was no documentation of training or on-going competency evaluations for all policies and procedures involved in compounding.

FIFTH CAUSE FOR DISCIPLINE

(Defective Compounding Quality Assurance Plan Against All Respondents)

54. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.8, subdivision (c), in that Respondents' Quality Assurance Plan for Non-Sterile Preparations did not include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, as set forth in paragraphs 42 through 47, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct Against Respondent Maii El-Shatanoufy)

55. Respondent Maii El-Shatanoufy is subject to disciplinary action under Code sections 4301(o) and (j), and Code section 4306.5 subdivision (a), for unprofessional conduct, in that Respondent Maii El-Shatanoufy did not ensure good compounding processes that were compliant with pharmacy law, which resulted in an error in the preparation of Amlodipine suspension and the demise of a dog, as set forth in paragraphs 42 through 47, which are incorporated herein by reference. Furthermore, Respondent El-Shatanoufy failed to appropriately exercise her education, training, and/or experience as explained in paragraphs 56 through 83 below, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Unlicensed Pharmacy Practice: Incorrect Public Signage Against All Respondents)

56. Respondents are subject to disciplinary action under Code sections 4301(o) and (j), and Code section 4110, subdivision (a), in that Respondents failed to display the licensed name of

"San Diego Optimum Compounding" during the inspections on September 11, 2020, September 20, 2021, and February 28, 2022.

EIGHTH CAUSE FOR DISCIPLINE

(Failure to Comply with Compounding Standards Against All Respondents)

57. Respondents are subject to disciplinary action under Code sections 4301(o) and (j), and Code section 4126.8 in that Respondents was not compliant with United States Pharmacopeia (USP)-National Formulary standard when at least the following occurred:

a. Gowns used for compounding were stored for reuse beyond the same shift.

b. Hair covers were stored for reuse.

c. During pre-sterilization steps were performed outside an ISO 8 environment.

d. Respondents failed to perform the required initial competency for individual involved with compounding.

e. Respondents assigned a 45 day beyond use date for frozen Glycerin compounds, however Glycerin cannot freeze at temperatures available in the pharmacy.

f. Viable sampling required three samples to be taken and only two were ever done.

g. Respondents assigned a 45 day beyond use date for frozen olive oil; however, olive oil cannot freeze at the temperatures available in the pharmacy.

NINTH CAUSE FOR DISCIPLINE

(Unauthorized Dispensing Against All Respondents)

58. Respondents are subject to disciplinary action under Code sections 4301(o) and (j), and Code section 4059, subdivision (a) in that Respondents dispensed the following six prescriptions between September 1, 2021, and January 20, 2022, written by RG, an unauthorized person who is licensed esthetician:

DRUG NAME	DOC NAME	RX NBR	RX DATE
TLC-2 AESTHETICS SL CREAM	RG	544670	1/17/2022
BENZ/LIDO/TETR 20-6-8% T CR	RG	541886	10/26/2021
TLC-4 Aesthetics SL cream	RG	544669	1/17/2022
Tretinoin 0.1%+HC 1% cream	RG	541437	1/11/2022

Tretinoin 0.1%+HC 1% cream	RG	541437	10/13/2021
Bernardo SPECIAL LIGHT.CR.	RG	531975	10/27/2021

TENTH CAUSE FOR DISCIPLINE

(Unprofessional Conduct-Making False Records Against All Respondents)

59. Respondents are subject to disciplinary action under Code section 4301, subdivision (g), in that during inspection on at least September 20, 2021, February 28, 2022, and September 12, 2022, Respondents' records were misleading as to the date a preparation was compounded as to the following:

a. Atropine 0.01% made September 15, 2021, but records showed it was made on September 20, 2021.

b. Compounding log for Iodine in almond oil RX 539474 stated it was made on September 20, 2021, however according to PIC El-Shatanoufy and TCH Moyer it was made on September 17, 2021.

c. Compounding log for Atropine 0.01% lot 210617@0.01CM for 60ml X 5 stated it was made on September 20, 2021, however according to PIC El-Shatanoufy and TCH Moyer it was made on September 17, 2021.

d. Compounding log showed lot 220228@0.2%CM, was made on February 25, 2022, but logged by CM on February 28, 2022.

e. Compounding log showed lot 220228@0.02CM was made on February 25, 2022, but logged by CM on February 28, 2022.

f. Compounding log showed lot 220228@0.06CM was made on February 25, 2022, but logged by CM on February 28, 2022.

g. Compounding order for lot 220228@1CM was made on February 25, 2022, but logged by CM on February 28, 2022.

h. Compounding log showed lot 220228@2CM was made on February 25, 2022, but logged by CM on February 28, 2022.

i. Compounding log showed lot 220228@30CM was made on February 25, 2022, but logged by CM on February 28, 2022.

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j. PIC El-Shatanoufy sent an email to the Board dated February 2, 2021, which stated RG was a Physician's Assistant, when in fact RG was a licensed esthetician.

k. Rx 546128, for Haloperidol 1mg/ml oral, BUD 3/11/22. Compounding log showed it was made on February 25, 2022, but beyond use date was assigned as if it was compounded on February 28, 2022. It was logged by TCH Moyer as compounded on February 28, 2022.

l. Training records provided on May 18, 2022, did not match records reviewed during the inspection on February 28, 2022.

m. On September 22, 2022, records related to Rx 553269 were obtained however, on October 27, 2022, the records received were inconsistent and false in that documents showed a different route of administration.

n. On October 27, 2022, when Respondent El-Shatanoufy provided a statement that no sterile product were dispensed from October 1, 2022, to October 25, 2022, this was a false statement for at least Hydroxocobalamin 20mg inj/sol Lot: 220930@9:45NM, which records show was dispensed after October 1, 2022.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Facilities, Space, Fixtures, and Equipment Against All Respondents)

60. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1714, subdivisions (b) and (c), in that during the inspections on July 31, 2020, September 11, 2020, September 20, 2021, and February 28, 2022, the pharmacy was found to be cluttered, in disarray, and was not maintained in a clean and orderly manner. Additionally, there was no sink dedicated for pharmaceutical purposes.

TWELFTH CAUSE FOR DISCIPLINE

(Variations from Prescriptions Against All Respondents)

61. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1716, in that Respondents deviated from the requirements of the prescription as follows:

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RX NBR	RX DATE	DRUG NAME	Dispensed as	Requirements of a Prescription
544670	1/17/22	TLC-2 AESTHETICS SL CREAM	Filled under RG, PA Filled as apply as directed to face every night at bedtime (must wear sunscreen > 50 SPF in the morning.)	Written by Dr. SS Directions for use: apply as directed to face QHS. Must wear sunscreen 30 or higher QAM.
544060	1/2/22	Apoquel 1.8mg/ml OO Susp	Oclacitinib tablet (Apoquel) were crush and labeled still as the branded product. Log show 60 (3.6mg tablet used) 316mgin ~61.2ml = 3.53mg/ml soln.	Written for Oclacitinib 1.8mg/ml
531975	10/27/21	Bernardo SPECIAL LIGHT.CR.	Filled under RG	Rx shows EV
553269	8/30/22	Dexamethasone	Dexamethasone 24mg/ml Otic solution	3 SOL Injection Dexamethasone 24mg/mli PF inj
542229	9/6/22	Gentamicin 0.4mg/ml	2 vials of 500ml	1vial of 1,000ml.

THIRTEENTH CAUSE FOR DISCIPLINE

(Dispensing Erroneous or Uncertain Prescriptions Against All Respondents)

62. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1761, subdivision (a) in that the following prescriptions were compounded and dispensed with significant error, omission, irregularity, uncertainty, ambiguity, or alteration:

RX NBR	RX DATE	DRUG NAME	Significant error, omission, irregularity, uncertainty, ambiguity or alteration
542609	11/16/2021	Glycerin48% IN Lido:Epi sol	No directions for use
544670	1/17/2022	TLC-2 AESTHETICS SL CREAM	Dispensed under an unauthorized prescriber
541886	10/26/2021	BENZ/LIDO/TETR 20-6-8% T CR	Dispensed under an unauthorized prescriber
544669	1/17/2022	TLC-4 Aesthetics SL cream	Dispensed under an unauthorized prescriber
541437	1/11/2022	Tretinoin 0.1%+HC 1% cream	Dispensed under an unauthorized prescriber
541437	10/13/2021	Tretinoin 0.1%+HC 1% cream	Dispensed under an unauthorized prescriber
531975	10/27/2021	Bernardo SPECIAL LIGHT.CR.	Dispensed under an unauthorized prescriber

FOURTEENTH CAUSE FOR DISCIPLINE

(Unlawful Office Dispensing Against All Respondents)

63. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (c), in that Respondents dispensed Rx 541886 for "BENZ/LIDO/TETR 20-6-8% T CR" 30 mg two jars for office dispensing, and no patient specific prescriptions were provided.

FIFTEENTH CAUSE FOR DISCIPLINE

(Unlawful Assignment of Beyond Use Date (BUD): Non-sterile Preparations Against All Respondents)

64. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (i)(1), in that on or about February 25, 2022, Respondents compounded haloperidol 1mg/ml oral (RX No. 546128) and assigned a seventeen day BUD, instead of the required fourteen day BUD.

SIXTEENTH CAUSE FOR DISCIPLINE

(Failure to Assign an Appropriate BUD: Sterile Preparations Against All Respondents)

65. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, sections 1751.8 and 1735.2, subdivision (i)(2) in that the following sterile preparations were assigned an inappropriate BUD:

number	Date	Drug
unknown	5/13/21	Voriconazole 10mg/ml eye drop
524252	2/25/20	Vancomycin 25mg/ml ophth
526200	5/28/20	Vancomycin 25mg/ml ophth
527877	7/31/20	Vancomycin 25mg/ml ophth
525014	3/24/20	Azelaci Acid 16.5% Top Gel
525371	4/15/20	Amphotericin 0.15% eye drop
543458	12/12/21	Fluorouracil-5 1% eye drops
545255	2/25/22	Piperacillin +Taz 12.5mg/ml
545237	2/25/22	Tobramycin 14mg/ml drops
546161	2/28/22	Chlorhexidine 0.02% drops
533358	10/27/21	Atropine 0.01% Eye Drop
534254	12/17/21	Atropine 0.01% Eye Drop
535446	11/1/21	Atropine 0.01% Eye Drop
535448	9/10/21	Atropine 0.01% Eye Drop
537808	11/11/21	Atropine 0.01% Eye Drop
538820	10/28/21	Atropine 0.01% Eye Drop
540493	10/26/21	Atropine 0.01% Eye Drop
540831	1/4/22	Atropine 0.01% Eye Drop

541086	12/9/21	Atropine 0.01% Eye Drop
541995	12/21/21	Atropine 0.01% Eye Drop
545964	2/22/22	Atropine 0.01% Eye Drop
545679	2/13/22	Atropine 0.01% Eye Drop
546117	2/24/22	Atropine 0.01% Eye Drop
545509	2/9/22	Atropine 0.01% Eye Drop
546004	2/22/22	Atropine 0.01% Eye Drop
526427	6/8/20	BiMix 5:30 injection
531133	11/24/20	hydroxocobalamin 25ml/ ml
544661	1/17/22	hydroxocobalamin 25ml/ ml
541834	1/28/22	hydroxocobalamin 30ml/ ml
527383	7/14/20	Glutathione 50mg/ml
527427	7/15/20	Glutathione 200mg/ml
525290	7/17/20	Glutathione 200mg/ml
527558	7/20/20	Glutathione 50mg/ml
525281	7/21/20	Glutathione 50mg/ml
unknown	7/22/20	Glutathione 500mg/ml
526231	5/29/20	Glycerin72% + Lido:epi 2:1 inj

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Support an Assigned Extended BUD Against All Respondents)

66. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.2, subdivision (i) in that the following compounds were assigned an extended BUD without the support of method suitability test, container closure integrity test, and stability studies:

Number	Date	Drug	Compounding review Lot number
533358	10/27/21	Atropine 0.01% Eye Drop	Lot 211027@0.01CM
534254	12/17/21	Atropine 0.01% Eye Drop	Lot 211217@0.01CM
535446	11/1/21	Atropine 0.01% Eye Drop	Lot 211104@0.01MS
535448	9/10/21	Atropine 0.01% Eye Drop	Lot 210914@0.01CM
537808	11/11/21	Atropine 0.01% Eye Drop	Lot 211110@0.01CM
538820	10/28/21	Atropine 0.01% Eye Drop	Lot 211027@0.01CM
540493	10/26/21	Atropine 0.01% Eye Drop	Lot 211025@0.01CM
540831	1/4/22	Atropine 0.01% Eye Drop	Lot 2210103@0.01CM
541086	12/9/21	Atropine 0.01% Eye Drop	Lot 211215@0.01CM
541995	12/21/21	Atropine 0.01% Eye Drop	Lot 211221@0.01CM
545964	2/22/22	Atropine 0.01% Eye Drop	Lot 220225@0.01CM
546117	2/24/22	Atropine 0.01% Eye Drop	unknown lot

546004	2/22/22	Atropine 0.01% Eye Drop	unknown lot
549249	9/8/22	Atropine 0.025% Eye Drop	Lot 220930@0.03CM
552216	9/30/22	Atropine 0.03% Eye Drop	Lot: 220927@0.01CM
547990	9/29/22	Atropine 0.01% Eye Drop	Lot 220929@0.02CM
546753	9/30/22	Atropine 0.02% Eye Drop	Lot 220930@0.05CM
541813	9/29/22	Atropine 0.05% Eye Drop	Lot 220930@0.03CM

In addition, 2,103 prescriptions for 13,909ml (2,782 bottles) of Atropine 0.01% eye drops dispensed from at least October 1, 2021, to January 20, 2022, were assigned an extended BUD without the support of support of method suitability test, container closure integrity test, and stability studies.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Keep Required Records of Compounding: Incomplete Compounding Log Against All Respondents)

67. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.3, subdivision (a), in that the following were incomplete compounding logs:

Number	Date	Drug	Compounding Review Lot Number
526427	6/8/20	BiMix 5:30 injection	Lot:200608@4:43NM
528763	8/28/20	Mitomycin 0.2ml opth	Lot: 200828@1:20NM
Unknown	6/23/20	Glutathione 500mg/ml	Lot: 200623@3CM
527383	7/14/20	Glutathione 50mg/ml	Lot: 200715@12:27NM
527427	7/15/20	Glutathione 200mg/ml	Lot: 200721@9:32NM
525290	7/17/20	Glutathione 200mg/ml	Lot: 200720@3:08NM
527558	7/20/20	Glutathione 50mg/ml	Lot: 200722@4:05NM
525281	7/21/20	Glutathione 50mg/ml	Lot: 200722@4:05NM
unknown	7/22/20	Glutathione 500mg/ml	Lot: 200722@3MS
526231	5/29/20	Glycerin72% + Lido:epi 2:1 inj	Lot:200601@2:17NM
527804	7/29/20	Azithromycin 100mg/ml inhalation	Lot 200731@3:50NM
unknown	5/13/21	Voriconazole 10mg/ml eye drop	Lot: 210513@2:18NM
524252	2/25/20	Vancomycin 25mg/ml ophth	No lot number

526200	5/28/20	Vancomycin 25mg/ml ophth	No lot number
525014	3/24/20	Azelaci Acid 16.5% Top Gel	Lot: 900604@4:15LN
525627	4/29/20	Naltrexone 0.5 IR caps	Lot: 20056@6MS
525854	5/11/20	Ketamine 150mg/ml nasal	Lot: 200502@NM
525371	4/15/20	Amphotericin 0.15% eye drop	Lot: 200526@NM
531133	11/24/20	hydroxocobalamin 25ml/ ml	Lot:210909@25CM
544661	1/17/22	hydroxocobalamin 25ml/ ml	Lot 220120@25CM10
541834	1/28/22	hydroxocobalamin 30ml/ ml	Lot 220201@30CM
533358	10/27/21	Atropine 0.01% Eye Drop	Lot 211027@0.01CM
534254	12/17/21	Atropine 0.01% Eye Drop	Lot 211217@0.01CM
535446	11/1/21	Atropine 0.01% Eye Drop	Lot 211104@0.01MS
535448	9/10/21	Atropine 0.01% Eye Drop	Lot 210914@0.01CM
537808	11/11/21	Atropine 0.01% Eye Drop	Lot 211110@0.01CM
538820	10/28/21	Atropine 0.01% Eye Drop	Lot 211027@0.01CM
540493	10/26/21	Atropine 0.01% Eye Drop	Lot 211025@0.01CM
540831	1/4/22	Atropine 0.01% Eye Drop	Lot 2210103@0.01CM
541086	12/9/21	Atropine 0.01% Eye Drop	Lot 211215@0.01CM
541437	1/11/22	Tretinoin 0.1%+HC 1% cream	Lot: 220113@2:57NM
541437	10/13/21	Tretinoin 0.1%+HC 1% cream	Lot 211014@11:54CM
541879	10/26/21	Glycolic 7.5+SA 2% top solu	Lot: 211026@1231NM
541886	10/26/21	BENZ/LIDO/TETR 20-6-8% T CR	Lot 211028@11:03LZ
541995	12/21/21	Atropine 0.01% Eye Drop	Lot 211221@0.01CM
542609	11/16/21	Glycerin48% IN Lido:Epi sol	Lot: 21119@48CM
543169	12/2/21	CERENIA 24MG/ML OO Susp	Lot 211203@2:25LZ
543242	1/4/22	CERENIA 24MG/ML OO Susp	Lot 220404@142:18NM
543242	12/16/21	CERENIA 24MG/ML OO Susp	Lot 211220@1217
543458	12/12/21	Fluorouracil-5 1% eye drops	Lot 211215@CM
544060	1/2/22	Apoquel 1.8mg/ml OO Susp	no lot number
544669	1/17/22	TLC-4 Aesthetics SL cream	no lot number
544670	1/17/22	TLC-2 AESTHETICS SL CREAM	no lot number
545255	2/25/22	Piperacillin +Taz 12.5mg/ml	Lot 220225@12.5CM
545237	2/25/22	Tobramycin 14mg/ml	Lot 220225@14CM
545964	2/22/22	Atropine 0.01% Eye Drop	Lot 220225@0.01CM 60 vials made
541403	1/5/22	Thymol 10% Topical Sol	Lot 220106@10%CM
542837	1/5/22	PHMB 0.02% eye drop	Lot 220106@0.02%CM
546071	2/25/22	Nifedipine 0.2% top oint	Lot 220228@0.2%CM

542721	2/24/22	Estriol 0.2% vag cream	Lot 220228@0.02CM
535879	2/24/22	Tretinoin 0.06%	Lot 220228@0.06CM
545985	2/22/22	Testosterone 2%	Lot 220228@2CM
546128	2/25/22	Haloperidol 1mg/ml	Lot 220228@1CM
552494 552095 552493 552079 552412 552029 551877 551973 X2 551725= 3ml 551634	6/30/22	EDTA 3% eye drops preservative fee 5ml	Lot:20630@12NM
545763	8/9/22	Trimix 10:1:30	Lot: 220809@12:30NM
553443	9/6/22	Tobramycin fortified 15mg/ml eyedrops	Lot: 220906@2:36NM
551736	7/21/22	Voriconazole Fortified 10mg/ml eyedrop	Lot 220721@2:14NM,
552199	8/2/22	Trimix 25:1:30	Lot: 220804@1.43NM
552100	8/2/22	Trimix 10:1:12 2.5 ml vial	Lot 220804@1:45NM
553163	8/29/22	Riboflav 0.1%	Lot 220829@3:30CM
553269	8/30/22	Dexamethasone 24mg/ml PF injection	Lot 220906@12:57NM
542299	5/25/22	Gentamicin 0.4mg/ ml Bladder Irrigation	Lot: 220525@0.4CM sterile to sterile
546118	8/30/22	Hydroxocobalamin 20mg inj/sol	Lot: 220901@
549249	9/8/22	Atropine 0.025% eye drop	no lot number
552216 547104	9/30/22	Atropine 0.03% eye drop	Lot 220930@0.03CM
547990	9/29/22	Atropine 0.01% eye drop	Lot: 220927@0.01CM
546753	9/30/22	Atropine 0.02% eye drop	Lot 220929@0.02CM
541814	9/29/22	Atropine 0.05% eye drop	Lot 220930@0.05CM
552141	6/2/22	Ceftazidime 50% opth	Lot: 220804@314NM
unknown	9/30/22	Ceftazidime 10% opth	Lot 220930@3NM
unknown	9/30/22	Ceftazidime 50% opth	Lot: 220930@3NM
553349	9/7/22	Ceftazidime 50mg/ml eye drops	Lot: 220908@2:06NM

551346	9/30/22	Chlorhexidine 0.02% ophthalmic	Lot:220914@12:29NM (high risk)
547452	9/29/22	"Bladder instillation" Heparin 66,000 U + lidocaine	Lot: 220929@11NM
unknown	9/30/22	Amphotericin B 10mcg/ml injection	Lot: 220930@9CM
554670	9/30/22	Phenol 4% in olive oil inj	Lot: 220926@4CM
unknown	9/29/22	Acetylcysteine 10% 5ml	Lot 220929@1NM

NINETEENTH CAUSE FOR DISCIPLINE

(Incorrect Labeling of a Sterile Compound Against All Respondents)

68. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.4, subdivision (a), in that the following sterile compounds were labeled incorrectly and incompletely:

Number	Date	Drug
526427	6/8/20	BiMix 5:30 injection
531975	10/27/21	Bernardo SPECIAL LIGHT.CR.
533358	10/27/21	Atropine 0.01% Eye Drop
534254	12/17/21	Atropine 0.01% Eye Drop
535446	11/1/21	Atropine 0.01% Eye Drop
535448	9/10/21	Atropine 0.01% Eye Drop
537808	11/11/21	Atropine 0.01% Eye Drop
538820	10/28/21	Atropine 0.01% Eye Drop
540493	10/26/21	Atropine 0.01% Eye Drop
540831	1/4/22	Atropine 0.01% Eye Drop
541086	12/9/21	Atropine 0.01% Eye Drop
541437	1/11/22	Tretinoin 0.1%+HC 1% cream
541437	10/13/21	Tretinoin 0.1%+HC 1% cream
541879	10/26/21	Glycolic 7.5+SA 2% top solu
541886	10/26/21	BENZ/LIDO/TETR 20-6-8% T CR
541995	12/21/21	Atropine 0.01% Eye Drop
542609	11/16/21	Glycerin48% IN Lido:Epi sol
543169	12/2/21	CERENIA 24MG/ML OO Susp
543242	1/4/22	CERENIA 24MG/ML OO Susp
543242	12/16/21	CERENIA 24MG/ML OO Susp
543458	12/12/21	Fluorouracil-5 1% eye drops
544060	1/2/22	Apoquel 1.8mg/ml OO Susp
544669	1/17/22	TLC-4 Aesthetics SL cream
544670	1/17/22	TLC-2 AESTHETICS SL CREAM
545255	2/25/22	Piperacillin +Taz 12.5mg/ml
552494 552095	6/30/22	EDTA 3% eye drops preservative fee 5ml

552493 552079 552412 552029 551877 551973 X2 551725= 3ml 551634		
545763	8/9/22	Trimix 10:1:30
552199	8/2/22	Trimix 25:1:30
552199	8/2/22	Trimix 25:1:30 SF
552100	8/2/22	Trimix 10:1:12 2.5 ml vial
552100	9/1522	Trimix 10:1:12 2.5 ml vial
553163	8/29/22	Riboflav 0.1%
553269	8/30/22	Dexamethasone 24mg/ml PF injection
542299	5/25/22	Gentamicin 0.4mg/ ml Bladder Irrigation
542299	9/6/22	Gentamicin 0.4mg/ ml Bladder Irrigation
546118	8/30/22	Hydroxocobalamin 20mg inj/sol
549249	9/8/22	Atropine 0.025% eye drop
552216 547104	9/30/22	Atropine 0.03% eye drop
547990	9/29/22	Atropine 0.01% eye drop
546753	9/30/22	Atropine 0.02% eye drop
552141	6/2/22	Ceftazidime 50% opth
unknown	9/30/22	Ceftazidime 10% opth
unknown	9/30/22	Ceftazidime 50% opth
551346	9/30/22	Chlorhexidine 0.02% ophthalmic
unknown	9/30/22	Amphotericin B 10mcg/ml injection
554670	9/30/22	Phenol 4% in olive oil inj
unknown	9/29/22	Acetylcysteine 10% 5ml

In addition, between September 1, 2021, and January 20, 2022, at least 284 prescriptions were dispensed without the name (brand or generic) of each active ingredient.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Follow the Pharmacies own Policies and Procedures Against All Respondents)

69. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.5, subdivision (a), and section 1751.3, subdivision (a), in that Respondents failed to follow their own Policies and Procedures as follows:

a. From at least June 2020, to March 2022, the ante-room was certified to ISO 8 when Policies and Procedures required the ante-room to be certified to ISO 7. The ante-room can

be engineered as an ISO 7 or ISO 8 environment. PIC El-Shatanoufy only updated after a written notice was issued on February 28, 2022.

b. The Policies and Procedures required compounding staff to complete a gloved fingertip sampling competency three (3) times before compounding responsibilities, there are no recording showing that the fingertip sampling competency occurred. PIC El-Shatanoufy was unaware of this requirement within her own policies and procedures until the February 28, 2022 inspection.

c. Policies and Procedures required the compounded sterile preparation (CSP) to be examined against a lighted white or black ground, or both. On February 28, 2022, PIC El-Shatanoufy was not able to explain how this was done since there was no light box available in the pharmacy.

d. Policies and Procedures required all NIOSH drugs be treated as Hazardous drugs and requires the pharmacy to follow USP 800 to be followed for compounding.

e. Policies and Procedures required surface sampling monthly and to sample the ISO 5 in three locations. Records provided for air and surface sampling only showed two total samples were taken. Further, it is unclear where the samples were taken (whether it was air or surface samples).

f. Policies and Procedures required, "[a]ll prepared compounding shall be send to an independent Lab to verify sterility and endotoxin." During the investigation, it was found that this did not occur and that in-house sterility testing was being conducted. This was a violation of Respondents' policy and procedure.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Keep Equipment Stored, Used, Maintained, and Cleaned in Accordance with Manufacturers' Specifications Against All Respondents)

70. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.6, subdivision (b), in that on or about September 20, 2021, and February 28, 2022, food grade mixers and household equipment was observed being used during compounding.

TWENTY-SECOND CAUSE FOR DISCIPLINE

(Preparing Sterile Compounding in a Noncompliant Location Against All Respondents)

71. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.6, subdivision (e) and 1751.4, subdivision (g), in that the following drug preparations occurred in a noncompliant location:

a. Mitomycin compounded on September 11, 2020;

b. Fluorouracil-5 1//5 1% eye drop compounded December 12, 2021;

c. Cyclosporine compounded on August 2, 2022 and August 31, 2022;

d. Tacrolimus compounded on August 10, 22, 16, 23 and September 6, 8, 2022; and

e. Testosterone compounded on August 25, 2022.

These drug preparations are required to be compounded in a negative pressure PEC and in an externally vented exhausted physically separate room.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Failure to Demonstrate Skill and Training for Against All Respondents)

72. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1735.7, subdivision (a), in that on or July 31, 2020, and September 11, 2020 records for training for pharmacist S.F. showed that she had not received training since 2017. On or about February 28, 2022, the inspection revealed that no pharmacy personnel assigned to compounding duties completed the initial gloved fingertip test.

TWENTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Have All Required Written Policies and Procedures for Compounding Against All Respondents)

73. Respondents are subject to disciplinary action under Code section 4301(o) for violating California Code of Regulations, title 16, section 1751.3, subdivision (a), in that the following required policies and procedures were never provided by Respondents:

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a. Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling.

b. An environmental sampling plan and procedures specific to viable air, surface, and gloved fingertip sampling as well as nonviable particle sampling.

c. For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time. This was developed in March 2022, only after a specific request.

TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Use Germicidal Detergent Daily Against All Respondents)

74. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (d), in that Respondents failed to provide evidence that germicidal detergent was used daily. During the inspection on September 20, 2021, Respondents' records failed to show daily cleaning of the compounding area with a germicidal detergent from September 16, 2021, to September 20, 2021, but the records showed that compounding took place on September 16, 17, and 20. Additionally, there is no evidence showing that germicidal detergent was used to clean the Glovebox. Further, the floors in the sterile compounding area were cleaned weekly, instead of daily, as required.

TWENTY-SIXTH CAUSE FOR DISCIPLINE

(Failure to Properly Store Cleaning Materials Against All Respondents)

75. Respondents are subject to disciplinary action under Code sections 4301(o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (d) in that the Respondents failed to properly store cleaning materials for compounding.

TWENTY-SEVENTH CAUSE FOR DISCIPLINE

(Failure to Maintain Sterile Compounding Area's Temperature Against All Respondents)

76. Respondents are subject to disciplinary action under Code sections 4301(o), for violating California Code of Regulations, title 16, section 1751.4, subdivision (k) in that the Respondents failed to maintain sterile compounding area's temperature. The logged temperature

was not typically cooler than 20 degree Celsius (68 degrees Fahrenheit) for May 2020-August 2020, January 2022-February 2022.

TWENTY-EIGHTH CAUSE FOR DISCIPLINE

(Failure to Conduct Initial Competency Evaluation Against All Respondents)

77. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7, subdivision (c) in that the Respondents failed to ensure that compounding staff completed the gloved fingertip sampling procedure.

TWENTY-NINTH CAUSE FOR DISCIPLINE

(Failure to Perform End Product Sterility Testing Against All Respondents)

78. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), in that the Respondents failed to perform end product sterility testing compliant with USP chapter 71 for the following prescriptions:

Number	Date	Drug
526427	6/8/20	BiMix 5:30 injection
525290	7/17/20	Glutathione 200mg/ml
527383	7/14/20	Glutathione 50mg/ml
527427	7/15/20	Glutathione 200mg/ml
525290	7/17/20	Glutathione 200mg/ml
unknown	5/13/21	Glycerin 48% in lido+epi sol inj
527558	7/20/20	Glutathione 50mg/ml
525281	7/21/20	Glutathione 50mg/ml
526231	5/29/20	Glycerin 72% + Lido:epi 2:1 inj
531133	11/24/20	Hydroxocobalamin 25ml/ ml
544661	1/17/22	Hydroxocobalamin 25ml/ ml
541834	1/28/22	Hydroxocobalamin 30ml/ ml

542609	11/16/21	Glycerin48% IN Lido:Epi sol
545763	8/9/22	Trimix 10:1:30
552199	8/2/22	Trimix 25:1:30
552199	8/2/22	Trimix 25:1:30 SF
552100	8/2/22	Trimix 10:1:12 2.5 ml vial
553163	8/29/22	Riboflav 0.1%
553269	8/30/22	Dexamethasone 24mg/ml PF inj
554670	9/30/22	Phenol 4% in olive oil inj
unknown	9/29/22	Acetylcysteine 10% 5ml

THIRTIETH CAUSE FOR DISCIPLINE

(Failure to Label Single-Dose Containers and Discard Against All Respondents)

79. Respondents are subject to disciplinary action under Code section 4301(o), for violating California Code of Regulations, title 16, section 1751.9, subdivision (b), in that the Respondents failed to label the puncture time on single dose containers. Since there was no puncture time labeled on the containers, the containers were required to be immediately discarded. Respondents failed to immediately discard the containers.

THIRTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Label, Store and Discard Multi-Dose Containers Against All Respondents)

80. Respondents are subject to disciplinary action under Code sections 4301(o), for violating California Code of Regulations, title 16, section 1751.9, subdivision (c) in that the Respondents failed to label the BUD on multi-dose containers. Since there was no BUD labeled on the containers, the containers were required to be immediately discarded. Respondents failed to immediately discard the containers.

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THIRTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Have Records Available for Review Against All Respondents)

81. Respondents are subject to disciplinary action under Code sections 4301(o) and (j), and Code section 4081, subdivision (a), in that the Respondents failed to have records available for review from September 12, 2022, to December 13, 2022, for the following records:

a. Dispensing records:

i. A list of all sterile compounds made with any items on "NIOSH list of Hazardous Drug Powders (updated Aug 1-2022)";

ii. Trimix 10:1:30 Lot:220809@12:30NM, for 4 vials;

iii. Voriconazole Lot:220721@2:14NM, for 2 vials; and

iv. Trimix 10:1:12 Lot:220804@1:45nm, for 2 vials.

b. Quality Assurance data for sterile preparations for 2022.

c. Data to support the following practices:

i. Stability of Gentamicin 0.4mg/ml bladder irrigation lot 220525@0.4CM in the freezer;

ii. Freeze/ thaw of papaverine and phentolamine used in trimix;

iii. Riboflavin 186508E is appropriate for use in for a sterile ophthalmic;

iv. Rapid-riboflavin 1mg/ml FDA approval label claim for "rapid";

v. Freezing of freezing of Bladder instillation (heparin + lidocaine);

vi. Freezing of Phenol 4% olive oil;

vii. Freezing of Amphotericin B; and

viii. Freezing of Glass 60ml vials, unknown manufacture.

d. Other requested information:

i. Study protocol for "primary cocktail for vet study".

THIRTY-THIRD CAUSE FOR DISCIPLINE

(Subverting an Investigation Against All Respondents)

82. Respondents are subject to disciplinary action under Code sections 4301, subdivision (q) in that the Respondents subverted the investigation as follows:

(a) Between September 12, 2022, and December 14, 2022, documents and records were requested from the pharmacy and never received;

(b) The records that were provided were inconsistent and contained false or inaccurate information;

(c) The records provided were incomplete and/or not legible; and

(d) Pharmacy staff was unable to provide requested information or answers.

THIRTY-FOURTH CAUSE FOR DISCIPLINE

(Failure to Have a Complete Quality Assurance Plan Against All Respondents)

83. Respondents are subject to disciplinary action under Code sections 4301(o), for violating California Code of Regulations, title 16, section 1735.8, subdivision (b) in that on or about September 12, 2022, during the inspection, the Respondents failed to have a complete quality assurance plan.

STATEMENT OF ISSUES AGAINST:

SAN DIEGO OPTIMUM COMPOUNDING

RENEWAL OF STERILE COMPOUNDING LICENSE

CAUSE FOR DENIAL

(Various)

84. Respondent San Diego Optimum Compounding's application to renew its sterile compounding license is subject to denial under Code sections 4127.7 (c), 4300 (c) and 4301 (j), (o), and (q) for violating the statutes and regulations referenced in the First Amended Accusation, which are incorporated herein by reference.

OTHER MATTERS

85. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831 issued to San Diego Optimum Compounding, Inc., dba San Diego Optimum Compounding, while Maii El-Shatanoufy was an officer and owner and had knowledge of or knowingly participated in any conduct for which licensee was disciplined, Maii El-Shatanoufy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for

five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding Licenses are reinstated, if they are revoked.

86. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number RPH 63672, issued to Maii El-Shatanoufy, Maii El-Shatanoufy shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 63672 is placed on probation or until Pharmacist License Number RPH 63672 is reinstated if it is revoked.

87. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831 issued to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding, it shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if the Pharmacy Permit and/or Sterile Compounding License are placed on probation or until the Pharmacy Permit and/or Sterile Compounding License are reinstated if they are revoked.

DISCIPLINE CONSIDERATIONS

88. To determine the degree of discipline, if any, to be imposed on Respondent San Diego Optimum Compounding, Complainant alleges that on or about October 17, 2019, the Board of Pharmacy issued Citation Number CI 2019 85363 and ordered Respondent to pay a fine in the amount of $500.00. In addition, an order of abatement was issued. The Citation was issued for violations of California Code of Regulations, title 16, section 1751.7, subdivision (e)(1) and Code section 4115, subdivision (f)(1) because no required end-product tested was completed and a single pharmacist was supervising two pharmacy technicians. That Citation is now final.

89. To determine the degree of discipline, if any, to be imposed on Respondent Maii El-Shatonoufy, Complainant alleges that on or about October 17, 2019, the Board of Pharmacy issued Citation Number CI 2019 85364 and ordered Respondent to pay a fine in the amount of $500.00. In addition, an order of abatement was issued. The Citation was issued for violations of California Code of Regulations, title 16, section 1751.7, subdivision (e)(1) and Code section

4115, subdivision (f)(1) because no required end-product tested was completed and a single pharmacist was supervising two pharmacy technicians. That Citation is now final.

90. To determine the degree of discipline, if any, to be imposed on Respondent San Diego Optimum Compounding, Complainant alleges that on or about June 5, 2018, the Board issued Citation Number CI 2016 71610 to Respondent. The Citation was issued for violations California Code of Regulations, title 16, section 1751.7, subdivision (b)(2) by failing to maintain freezer temperature logs for the storage of compounded sterile BiMix for injections.

91. To determine the degree of discipline, if any, to be imposed on Respondent San Diego Optimum Compounding, Complainant alleges that on or about November 26, 2019, the Board issued Citation Number CI 2019 86038 and ordered Respondent to pay a fine in the amount of $500.00. In addition, an order of abatement was issued. The Citation was for the following violations:

i. Failure to maintain the quality of a compounded sterile preparations in violation of California Code of Regulations, title 16, section 1735.1 .7, subdivision (ae) and section 1735.(2), subdivision (g).

ii. Adulterated preparation in violation of Health and Safety Code sections 11250 and 222395 and Code section 4169, subdivision (a)(2).

iii. Failure to have complete compounding records in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(F)(J).

92. To determine the degree of discipline, if any, to be imposed on Respondent Maii El-Shatanoufy, Complainant alleges that on or about November 26, 2019, the Board issued Citation Number CI 2019 86039 and ordered Respondent Maii El- Shatanoufy to pay fines in the amount of $3,000.00 for the following violations:

i. Failure to maintain the quality of a compounded sterile preparation in violation of California Code of Regulations, title 16, section 1735.1 .7, subdivision (ae) and section 1735.(2), subdivision (g).

ii. Adulterated preparation in violation of Health and Safety Code sections 11250 and 222395 and Code section 4169, subdivision (a)(2).

iii. Failure to have complete compounding records in violation of California Code of Regulations, title 16, section 1735.3, subdivision (a)(F)(J).

93. To determine the degree of discipline, if any, to be imposed on Respondent Maii El-Shatanoufy, Complainant alleges that on or about October 18, 2018, the Board issued a letter of admonishment to Respondent for failure to maintain a freezer temperature log in violation of Code section 4315 and California Code of Regulations, title 16, section 1751.1 subdivision (b)(2).

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. Revoking or suspending Pharmacy Permit Number PHY 53633, issued to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding, Maii El-Shatanoufy, CEO;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100831, issued to San Diego Optimum Compounding, Inc. dba San Diego Optimum Compounding, Maii El-Shatanoufy, CEO;

3. Revoking or suspending Pharmacist License Number RPH 63672, issued to Maii El-Shatanoufy;

4. Prohibiting Maii El-Shatanoufy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831 is placed on probation or until Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831 reinstated if they are revoked;

5. Prohibiting Maii El-Shatanoufy from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License Number RPH 63672 is placed on probation or until Pharmacist License Number RPH 63672 is reinstated if it is revoked;

6. Prohibiting San Diego Optimum Compounding, Inc. from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831

is placed on probation or until Pharmacy Permit Number PHY 53633 and/or Sterile Compounding Permit Number LSC 100831 is reinstated if they are revoked;

7. Denying the Renewal of Sterile Compounding Permit Number LSC 100831;

8. Ordering Maii El-Shatanoufy to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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

DATED: 4/26/2023

Sodergren, Anne@DCA

Digitally signed by Sodergren, Anne@DCA
Date: 2023.04.26 20:38:43 -07'00'

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

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