XAVIER BECERRA
Attorney General of California
ANTOINETTE B. CINCOTTA
Supervising Deputy Attorney General
BRIAN WEISEL
Deputy Attorney General
State Bar No. 251111
600 West Broadway, Suite 1800
San Diego, CA 92101
P.O. Box 85266
San Diego, CA 92186-5266
Telephone: (619) 738-9089
Fax: (619) 645-2061
E-mail: Brian.Weisel@doj.ca.gov
Attorneys for Complainant

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

In the Matter of the Accusation Against**:** **PARK COMPOUNDING INC.** **DBA PARK COMPOUNDING** **F.K.A. IMPRIMISRX** **9257 Research Drive** **Irvine, CA 92618** **Pharmacy Permit No. PHY 53360** **Sterile Compounding License No. LSC 100771** **MARIAM SAAD FOUAD BEKHIT ELGAWLY** **652 Marketview** **Irvine, CA 92602** **Pharmacist License No. RPH 74911** **NADIA MOHAMED ELSAYED IBRAHIM** **162 Calle De Los Ninos** **Rancho Santa Margarita, CA 92688** **Pharmacist License No. RPH 55103** **RONAK AMIT DESAI** **16611 Maurice Circle** **Cerritos, CA 90703** **Pharmacist License No. RPH 55481** Respondents.	Case No. 6271 **SECOND AMENDED ACCUSATION**

Complainant alleges:

PARTIES

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

2. On or about August 26, 2015, the Board issued Pharmacy Permit Number PHY 53360 to Imprimis Pharmaceuticals, Inc. and South Coast Specialty Compounding, Inc., doing business as Park Compounding. On June 1, 2016, South Coast Specialty Compounding, Inc. became known as Imprimis Pharmaceuticals, Inc., doing business as ImprimisRx (Respondent Park Compounding[1]). On November 7, 2017, ImprimisRx became known as Park Compounding, Inc., doing business as Park Compounding. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2019, unless renewed.

3. On or about August 26, 2015, the Board issued Sterile Compounding License No. LSC 100771 to Imprimis Pharmaceuticals, Inc. and South Coast Specialty Compounding, Inc., doing business as Park Compounding. On June 1, 2016, South Coast Specialty Compounding, Inc. became known as Imprimis Pharmaceuticals, Inc., doing business as ImprimisRx. On November 7, 2017, ImprimisRx became known as Park Compounding, Inc., doing business as Park Compounding. The Sterile Compounding License was in full force and effect at all times relevant to the charges brought herein and will expire on August 1, 2019, unless renewed.

4. On or about August 22, 2016, the Board issued Pharmacist License Number RPH 74911 to Mariam Saad Fouad Bekhit ElGawly (Respondent ElGawly). The Pharmacist License was in full force and effect at all times relevant to the charges and allegations brought herein and will expire on February 28, 2020, unless renewed.

5. On or about September 16, 2003, the Board issued Pharmacist License Number RPH 55103 to Nadia Mohamed Elsayed Ibrahim (Respondent Ibrahim). The Pharmacist License was

[1] Though the facility changed names at different times relevant to this Accusation, Respondent facility is referenced at all times herein as "Park Compounding."

in full force and effect at all times relevant to the charges and allegations brought herein and will expire on August 31, 2019, unless renewed.

6. On or about June 23, 2004, the Board issued Pharmacist License Number RPH 55481 to Ronak A. Desai (Respondent Desai). The Pharmacist License was in full force and effect at all times relevant to the charges and allegations brought herein and will expire on February 29, 2020, unless renewed.

JURISDICTION

7. This Second Amended Accusation is brought before the Board, , under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

8. Section 4011 of the Code 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.].

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

10. Section 4300.1 of the Code 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.

STATUTORY AND REGULATORY PROVISIONS

11. Section 651, subdivision (a) of the Code states:

> (a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to disseminate or cause to be disseminated any form of public communication containing a false, fraudulent, misleading, or deceptive statement, claim, or image for the purpose of or likely to induce, directly or indirectly, the rendering of professional services or furnishing of products in connection with the professional practice or business for which he or she is licensed. A "public communication" as used in this section includes, but is not limited to, communication by means of mail, television, radio, motion picture, newspaper, book, list or directory of healing arts practitioners, Internet, or other electronic communication.

(b) A false, fraudulent, misleading, or deceptive statement, claim, or image includes a statement or claim that does any of the following:

(1) Contains a misrepresentation of fact.

(2) Is likely to mislead or deceive because of a failure to disclose material facts.

(3) (A) Is intended or is likely to create false or unjustified expectations of favorable results, including the use of any photograph or other image that does not accurately depict the results of the procedure being advertised or that has been altered in any manner from the image of the actual subject depicted in the photograph or image.

(B) Use of any photograph or other image of a model without clearly stating in a prominent location in easily readable type the fact that the photograph or image is of a model is a violation of subdivision (a). For purposes of this paragraph, a model is anyone other than an actual patient, who has undergone the procedure being advertised, of the licensee who is advertising for his or her services.

(C) Use of any photograph or other image of an actual patient that depicts or purports to depict the results of any procedure, or presents "before" and "after" views of a patient, without specifying in a prominent location in easily readable type size what procedures were performed on that patient is a violation of subdivision (a). Any "before" and "after" views (i) shall be comparable in presentation so that the results are not distorted by favorable poses, lighting, or other features of presentation, and (ii) shall contain a statement that the same "before" and "after" results may not occur for all patients.

(4) Relates to fees, other than a standard consultation fee or a range of fees for specific types of services, without fully and specifically disclosing all variables and other material factors.

(5) Contains other representations or implications that in reasonable probability will cause an ordinarily prudent person to misunderstand or be deceived.

(6) Makes a claim either of professional superiority or of performing services in a superior manner, unless that claim is relevant to the service being performed and can be substantiated with objective scientific evidence.

(7) Makes a scientific claim that cannot be substantiated by reliable, peer reviewed, published scientific studies.

(8) Includes any statement, endorsement, or testimonial that is likely to mislead or deceive because of a failure to disclose material facts.

(c) Any price advertisement shall be exact, without the use of phrases, including, but not limited to, "as low as," "and up," "lowest prices," or words or phrases of similar import. Any advertisement that refers to services, or costs for services, and that uses words of comparison shall be based on verifiable data substantiating the comparison. Any person so advertising shall be prepared to provide information sufficient to establish the accuracy of that comparison. Price advertising shall not be fraudulent, deceitful, or misleading, including statements or advertisements of bait, discount, premiums, gifts, or any statements of a similar nature. In connection with price advertising, the price for each product or service shall be clearly identifiable. The price advertised for products shall include charges

for any related professional services, including dispensing and fitting services, unless the advertisement specifically and clearly indicates otherwise.

(d) Any person so licensed shall not compensate or give anything of value to a representative of the press, radio, television, or other communication medium in anticipation of, or in return for, professional publicity unless the fact of compensation is made known in that publicity.

(e) Any person so licensed may not use any professional card, professional announcement card, office sign, letterhead, telephone directory listing, medical list, medical directory listing, or a similar professional notice or device if it includes a statement or claim that is false, fraudulent, misleading, or deceptive within the meaning of subdivision (b).

(f) Any person so licensed who violates this section is guilty of a misdemeanor. A bona fide mistake of fact shall be a defense to this subdivision, but only to this subdivision.

(g) Any violation of this section by a person so licensed shall constitute good cause for revocation or suspension of his or her license or other disciplinary action.

(h) Advertising by any person so licensed may include the following:

(1) A statement of the name of the practitioner.

(2) A statement of addresses and telephone numbers of the offices maintained by the practitioner.

(3) A statement of office hours regularly maintained by the practitioner.

(4) A statement of languages, other than English, fluently spoken by the practitioner or a person in the practitioner's office.

(5) (A) A statement that the practitioner is certified by a private or public board or agency or a statement that the practitioner limits his or her practice to specific fields.

(B) A statement of certification by a practitioner licensed under Chapter 7 (commencing with Section 3000) shall only include a statement that he or she is certified or eligible for certification by a private or public board or parent association recognized by that practitioner's licensing board.

(C) A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California may include a statement that he or she limits his or her practice to specific fields, but shall not include a statement that he or she is certified or eligible for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, unless that board or association is (i) an American Board of Medical Specialties member board, (ii) a board or association with equivalent requirements approved by that physician's and surgeon's licensing board prior to January 1, 2019, or (iii) a board or association with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in that specialty or subspecialty. A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by an organization other than a board or association referred to in clause (i), (ii), or

(iii) shall not use the term "board certified" in reference to that certification, unless the physician and surgeon is also licensed under Chapter 4 (commencing with Section 1600) and the use of the term "board certified" in reference to that certification is in accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5 (commencing with Section 2000) by the Medical Board of California who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the Medical Board of California, for certifying medical doctors and other health care professionals that is based on the applicant's education, training, and experience. A multidisciplinary board or association approved by the Medical Board of California prior to January 1, 2019, shall retain that approval.

For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is an American Board of Medical Specialties member board, an organization with equivalent requirements approved by a physician's and surgeon's licensing board prior to January 1, 2019, or an organization with an Accreditation Council for Graduate Medical Education approved postgraduate training program that provides complete training in a specialty or subspecialty.

(D) A doctor of podiatric medicine licensed under Article 22 (commencing with Section 2460) of Chapter 5 by the California Board of Podiatric Medicine may include a statement that he or she is certified or eligible or qualified for certification by a private or public board or parent association, including, but not limited to, a multidisciplinary board or association, if that board or association meets one of the following requirements: (i) is approved by the Council on Podiatric Medical Education, (ii) is a board or association with equivalent requirements approved by the California Board of Podiatric Medicine, or (iii) is a board or association with the Council on Podiatric Medical Education approved postgraduate training programs that provide training in podiatric medicine and podiatric surgery. A doctor of podiatric medicine licensed under Article 22 (commencing with Section 2460) of Chapter 5 by the California Board of Podiatric Medicine who is certified by a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" unless the full name of the certifying board is also used and given comparable prominence with the term "board certified" in the statement. A doctor of podiatric medicine licensed under Article 22 (commencing with Section 2460) of Chapter 5 by the California Board of Podiatric Medicine who is certified by an organization other than a board or association referred to in clause (i), (ii), or (iii) shall not use the term "board certified" in reference to that certification.

For purposes of this subparagraph, a "multidisciplinary board or association" means an educational certifying body that has a psychometrically valid testing process, as determined by the California Board of Podiatric Medicine, for certifying doctors of podiatric medicine that is based on the applicant's education, training, and experience. For purposes of the term "board certified," as used in this subparagraph, the terms "board" and "association" mean an organization that is a Council on Podiatric Medical Education approved board, an organization with equivalent requirements approved by the California Board of Podiatric Medicine, or an organization with a Council on Podiatric Medical Education approved postgraduate training program that provides training in podiatric medicine and podiatric surgery.

The California Board of Podiatric Medicine shall adopt regulations to establish and collect a reasonable fee from each board or association applying for recognition pursuant to this subparagraph, to be deposited in the State Treasury in the Podiatry Fund, pursuant to Section 2499. The fee shall not exceed the cost of administering this subparagraph.

(6) A statement that the practitioner provides services under a specified private or public insurance plan or health care plan.

(7) A statement of names of schools and postgraduate clinical training programs from which the practitioner has graduated, together with the degrees received.

(8) A statement of publications authored by the practitioner.

(9) A statement of teaching positions currently or formerly held by the practitioner, together with pertinent dates.

(10) A statement of his or her affiliations with hospitals or clinics.

(11) A statement of the charges or fees for services or commodities offered by the practitioner.

(12) A statement that the practitioner regularly accepts installment payments of fees.

(13) Otherwise lawful images of a practitioner, his or her physical facilities, or of a commodity to be advertised.

(14) A statement of the manufacturer, designer, style, make, trade name, brand name, color, size, or type of commodities advertised.

(15) An advertisement of a registered dispensing optician may include statements in addition to those specified in paragraphs (1) to (14), inclusive, provided that any statement shall not violate subdivision (a), (b), (c), or (e) or any other section of this code.

(16) A statement, or statements, providing public health information encouraging preventive or corrective care.

(17) Any other item of factual information that is not false, fraudulent, misleading, or likely to deceive.

(i) Each of the healing arts boards and examining committees within Division 2 shall adopt appropriate regulations to enforce this section in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Each of the healing arts boards and committees and examining committees within Division 2 shall, by regulation, define those efficacious services to be advertised by businesses or professions under their jurisdiction for the purpose of determining whether advertisements are false or misleading. Until a definition for that service has been issued, no advertisement for that service shall be disseminated. However, if a definition of a service has not been issued by a board or committee within 120 days of receipt of a request from a licensee, all those holding the license may advertise the service. Those boards and committees shall adopt or modify

regulations defining what services may be advertised, the manner in which defined services may be advertised, and restricting advertising that would promote the inappropriate or excessive use of health services or commodities. A board or committee shall not, by regulation, unreasonably prevent truthful, nondeceptive price or otherwise lawful forms of advertising of services or commodities, by either outright prohibition or imposition of onerous disclosure requirements. However, any member of a board or committee acting in good faith in the adoption or enforcement of any regulation shall be deemed to be acting as an agent of the state.

(j) The Attorney General shall commence legal proceedings in the appropriate forum to enjoin advertisements disseminated or about to be disseminated in violation of this section and seek other appropriate relief to enforce this section. Notwithstanding any other provision of law, the costs of enforcing this section to the respective licensing boards or committees may be awarded against any licensee found to be in violation of any provision of this section. This shall not diminish the power of district attorneys, county counsels, or city attorneys pursuant to existing law to seek appropriate relief.

(k) A physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) by the Medical Board of California or a doctor of podiatric medicine licensed pursuant to Article 22 (commencing with Section 2460) of Chapter 5 by the California Board of Podiatric Medicine who knowingly and intentionally violates this section may be cited and assessed an administrative fine not to exceed ten thousand dollars ($10,000) per event. Section 125.9 shall govern the issuance of this citation and fine except that the fine limitations prescribed in paragraph (3) of subdivision (b) of Section 125.9 shall not apply to a fine under this subdivision.

12. Section 4081 of the Code states in pertinent part:

(a) All records of manufacture and of sale, acquisition, 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, pharmacy, veterinary food animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, 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.

(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food animal drug retailer shall be jointly responsible, with the pharmacist in charge or representative-in-charge, for maintaining the records and inventory described in this section.

. . .

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for all least three year from the date of making. The records shall be at all times during business hours open to inspection by authorizes officers of the law.

13. Section 4105, subdivision (a) of the Code states in pertinent part:

All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

14. Sections 4169, subdivisions (a)(1) - (a)(5) of the Code states:

(a) A person or entity shall not do any of the following:

(1) Purchase, trade, sell, warehouse, distribute, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler, third-party logistics provider, or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Divison 104 of the Health and Safety Code.

(3) Purchase, trade, sell or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the

Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

15. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(c) Gross negligence.

…

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

…

(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, or 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 any other state or federal regulatory agency.

…

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

…

16. Section 4113, subdivision (c) of the Code states:

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.

17. Section 4127.1, subdivision (f) of the Code states:

Adverse effects reported or potentially attributable to a pharmacy's sterile drug product shall be reported to the board within 12 hours and immediately reported to the MedWatch program of the federal Food and Drug Administration.

18. Section 4307, subdivision (a) of the Code states that:

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, or partner of any partnership, corporation, 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 manger, administrator, owner, member, officer, director, associate, or partner had knowledge 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 manger, administrator, owner, member, officer, director, associate, or partner 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.

19. Health and Safety Code section 110390 states:

It is unlawful for any person to disseminate any false advertisement of any food, drug, device or cosmetic. An advertisement is false if it is false or misleading in any particular.

20. Health and Safety Code section 111250 states:

Any drug or device is adulterated if it consists, in whole or in part, of any filthy, putrid, or decomposed substance.

21. Health and Safety Code section 111255 states:

Any drug or device is adulterated if it has been produced, prepared, packed, or held under conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

22. Health and Safety Code section 111295 states:

It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated.

23. Health and Safety Code section 111300 states:

It is unlawful for any person to adulterate any drug or device.

24. Health and Safety Code section 111375(c) states:

Every drug or device is misbranded unless its labeling bears all of the following information. Adequate warning against unsafe dosage or methods or duration of administration or application. Warnings shall be in a manner and form as are necessary for the protection of users.

25. Health and Safety Code section 111440 states:

It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

26. Health and Safety Code section 111425 states:

A drug is misbranded if it was manufactured in this state in an establishment not duly licensed as provided in this part.

27. Health and Safety Code section 111445 states:

It is unlawful for any person to misbrand any drug or device.

28. Health and Safety Code section 111450 states:

It is unlawful for any person to receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery any drug or device.

/ / /

29. California Code of Regulations, title 16, section 1735.2, subdivision (i)(3) states:

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

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.

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

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.

31. California Code of Regulations, title 16, sections 1735.4, subdivisions (a) and (b) state:

(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.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

32. California Code of Regulations, title 16, sections 1751.7, subdivision (e)(1) states:

Batched-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.

33. California Code of Regulations, title 16, sections 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

34. 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.

DRUGS

35. Polyethylene Glycol Castor Oil (PEG) is an emulsifier aiding oil-in-water formulations. In hypersensitive patients, PEG can cause severe and sometimes fatal reactions.

36. Artesunate is a semisynthetic derivative of artemisinin; however, artesunate and artemisinin are separate and distinct bulk drug substances. Artesunate is used in some countries to treat malaria; however, it is not approved for any use by the United States Food and Drug Administration (FDA).

37. Curcumin is the principal curcuminoid of the turmeric root that may have antioxidant or anti-inflammatory effects. To date, the FDA has not approved curcumin for injection products.

FACTUAL ALLEGATIONS

38. From January 23, 2017 through May 29, 2017, Respondent ElGawly was the Pharmacist-in-Charge (PIC) of Respondent Park Compounding. From July 24, 2017 through December 5, 2017, Respondent Desai was the PIC of Respondent Park Compounding. From December 6, 2017 to the December 5, 2018, Respondent Ibrahim was the PIC of Respondent Park Compounding. Respondent Park Compounding compounded and dispensed sterile injectable drug preparations and other human drug products. Respondent Park Compounding is not registered as a Registered Outsourcing Facility pursuant to section 503B of the Federal Food, Drug, and Cosmetic Act (503B outsourcer) with the FDA nor does it hold a valid license with the California State Department of Public Health.

39. Respondent Park Compounding possessed written policies and procedures for recalling a dispensed compounded drug preparation where subsequent information demonstrated the potential for adverse effects with continued use. Specifically, Respondent Park Compounding's policies and procedures entitled "Handling Products Recalls" stated that a recall

will be initiated if "a determination subsequent to the dispensing of a prescription that the medication may not have met specifications for preparation, content, sterility and/or quality or may present a risk to patients."

40. On May 23, 2017, Board inspectors conducted a routine inspection of Respondent Park Compounding, located in Irvine, California. The paint around the door knob of the clean room was chipped. Respondent Elagawly told inspectors that they would have the paint touched up. Bottles of sterile isopropyl alcohol were not dated with the time of opening.

41. Inspectors showed an invoice from Respondent Park Compounding to pharmacist DS, who confirmed the invoice and that Respondent Park Compounding had shipped drugs to the New Jersey facility, which was not licensed by the California Board. Pursuant to the invoice, among the drugs shipped out-of-state were:

Date	Drug and quantity	Cost
1/16/2017	Epinephrine 5gm	$357.00
4/10/17	Moxifloxacin 500gm	$620.00
4/10/17	Timolol 15gm	$375.00
4/10/17	Brimonidine 6gm	$1,500.00
4/10/17	Dorzolamide	$2,250.00
4/11/17	Latanoprost 1gm	$3,900.00
4/12/19	Hyaluronidase 1.4 gm	$2,989.65

Compounding and Dispensing Human Drug Products made with Curcumin.

42. From January 13, 2017 through June 15, 2017, Respondent Park Compounding compounded a sterile injectable drug preparation, curcumin emulsion. Respondent Park Compounding compounded that drug preparation with an excipient, PEG 40 castor oil (No. P2404). The PEG 40 castor oil used by Respondent Park Compounding contained higher than detectable levels (i.e., greater than 0.1%) of a contaminant or poison, diethylene glycol (DEG) and was not intended for human consumption. Indeed, the labels on PEG 40 castor oil used to compound curcumin emulsion by Respondent Park Compounding warned, **"CAUTION:** for

manufacturing and laboratory use only. **Read and understand the label and Safety Data Sheet (SDS) prior to use"** (emphasis in original). The Precautions section of the Safety Data Sheets provided that PEG 40 castor oil should not be ingested and that "if ingested, seek medical advice immediately and show the container or the label." The Toxicological Information section noted that "ingestion...PEG may be a human allergen or hapten. Anaphylaxis may occur following ingestion of PEG."

43. From January 11, 2017 through February 23, 2017, Respondent Park Compounding assigned beyond use dates for curcumin emulsion which were not supported by any method suitability tests, container closure integrity tests and/or stability studies.

44. From January 13, 2017 through June 15, 2017, Respondent Park Compounding dispensed curcumin emulsion to patients without necessary patient specific information, including the weight and allergies of each specific patient. Curcumin emulsion is a dosed based drug based on a patient's weight but Respondents failed to even record patients' weight, let alone calibrate the doses accordingly.

45. From January 9, 2017 through April 14, 2017, Respondent Park Compounding dispensed curcumin emulsion without labels warning about hypersensitivity reactions associated with the PEG 40 castor oil (No. P2404).

46. On February 8, 2017, Respondent Park Compounding dispensed curcumin emulsion to the wife of a naturopathic physician, K.K.

47. On March 10, 2017, Dr. K.K. administered that curcumin emulsion compounded by Respondents to a 30-year old patient, J.E., via an infusion for the treatment of a skin disorder. Patient J.E., had an anaphylactic reaction, was taken to the emergency room of a hospital and subsequently died.

48. The vial of curcumin emulsion compounded by Respondent Park Compounding and administered to patient J.E., and the lots from which that vial was derived, contained higher than detectable levels (i.e., greater than 0.1%) of DEG.

49. On March 16, 2017, Respondent Park Compounding dispensed curcumin emulsion to a naturopathic nurse practitioner, S.G.

50. On March 17, 2017, Respondent Park Compounding reported J.E.'s adverse effects to the curcumin emulsion to the Board even though it learned of those adverse effects on March 13, 2017. Respondent Park Compounding did not voluntarily recall its curcumin emulsion within expiry nor suspend the compounding of curcumin emulsion.

51. On March 20, 2017, the FDA issued a warning letter to Respondent Park Compounding based on the FDA's inspections, noting "serious deficiencies in [Respondent Park Compounding's] practices for producing sterile drug products, which put patients at risk" and the issuance of a Form FDA 483 to Respondent Park Compounding on March 14, 2016.[2] The FDA concluded that Respondent Park Compounding appeared to produce drug products that violated the Federal Food, Drug and Cosmetic Act, including the production of adulterated drug products. (FDA noted that "drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health causing [Respondent Park Compounding's] drug products to be adulterated under section 501(a)(2)(A) of the FDCA"). The FDA strongly recommended that Respondent Park Compounding's management "undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations."

52. On March 22, 2017, Respondent Elgalwy represented to the Board that the facility had completed its investigation of the compounding of the curcumin emulsion administered to J.E. and found "no excursions" in their compounding of the curcumin emulsion at issue.

53. On March 31, 2017, the FDA issued another Form FDA 483 to Park Compounding, observing, among other things, that Park Compounding's "aseptic processing areas [were] deficient regarding air supply that is filtered through high-efficiency particulate air filters under positive pressure" and that Respondent Park Compounding had 69 Quality Related Events (QRE), including ADEs [adverse drug events] and product quality complaints" in 2016 and the first quarter of 2017.

[2] The July 2, 2014 Form 483 cited seven potential Current Good Manufacturing Practices violations, including a finding that "each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements."

54. On or about May 4, 2017, Nurse Practitioner S.G. administered curcumin emulsion compounded by Park Compounding to a patient, W.K. who was subsequently admitted to an emergency room of a hospital with an anaphylactic reaction.

55. On May 8, 2017, Respondent Park Compounding reported W.K.'s adverse effects to the curcumin emulsion to the Board even though it learned of W.K.'s adverse effects on May 4, 2017. Respondent Park Compounding did not voluntarily recall its curcumin emulsion within expiry or suspend the compounding or dispensing of curcumin emulsion.

56. On June 1, 2017, the FDA informed Respondent Park Compounding that preliminary lab analysis identified DEG at approximately 0.2% in samples of curcumin 10 mg/mL emulsion compounded by Respondents and that the FDA considered the use of PEG 40 castor oil to be inappropriate for the compounding of human drug products.

57. On June 1, 2017, the FDA requested Respondent Park Compounding to voluntarily recall curcumin emulsion containing PEG 40 castor oil and informed Respondent Park Compounding that the DEG in the PEG 40 castor oil (No. P2404) was at detectable levels. Respondent Park Compounding refused to do so, but did suspend the compounding and dispensing of curcumin emulsion. Respondent Park Compounding requested that its wholesaler perform testing to determine the potency of DEG in PEG 40 castor oil (No. P2402) used by Respondent Park Compounding.

58. On June 15, 2017, the FDA requested again that Respondent Park Compounding voluntarily recall the curcumin emulsion compounded by it, but Respondent Park Compounding refused to do so.

59. On June 19, 2017, after Respondent Park Compounding was told twice by the FDA and the Board that Respondent Park Compounding's curcumin emulsion did not met specifications and presented a risk to patients, Respondent Park Compounding recalled its curcumin emulsion containing PEG 40 castor oil (No. P2404) within expiry. In its recall notice, Respondent Park Compounding stated that it was recalling all affected lots of curcumin emulsion because the FDA notified Respondent Park Compounding that "one of its suppliers mislabeled an inactive ingredient contained in small quantities in the [affected] lots" of curcumin emulsion.

60. On August 4, 2017, the FDA released a MedWatch which stated, in pertinent part, "FDA's investigation into the adverse events associated with [Respondent Park Compounding]'s curcumin emulsion product for injection highlights some of the risks associated with compounded drugs, particularly those that use non-pharmaceutical grade components and ingredients lacking a USP monograph. The risks illustrated in this case include: the absence of a label warning about hypersensitivity reactions associated with the PEG 40 castor oil (No. P2404), the use of an ungraded inactive ingredient, i.e., PEG 40 castor oil (No. P2404), that is not suitable for human consumption or therapeutic use and may contain impurities such as DEG; and the IV administration of curcumin, even though its safety profile by this route of administration has not been established, nor has its effectiveness in treating eczema or thrombocytopenia."

61. On August 7, 2017, Respondent Park Compounding denied responsibility for improperly compounding the unsafe curcumin emulsion, issuing a press release in which it blamed the victim, physician and supplier for the events at issue and contending that its compounding and dispensing of curcumin emulsion were in compliance with all applicable laws.

62. On August 22, 2017, and in response to the Board's inquiry, Respondent Park Compounding represented that preliminary results showed that DEG levels in the curcumin emulsion compounded by it were at or below required amounts even though the FDA informed them on June 1, 2017, that the FDA had preliminarily tested Respondent Park Compounding's curcumin emulsion and determined that the DEG levels in the excipient, PEG 40 castor oil (No. P2404) were actually above the detectable 0.1% limit.

63. Despite receiving five requests from the Board, Respondent Park Compounding failed to produce all records requested by the Board, including prescriptions. Respondent Park Compounding's dispensing records were incomplete including prescriptions which did not list the pharmacist who dispensed curcumin emulsion.

/ / /

/ / /

/ / /

Compounding and Dispensing Human Drug Products made with Artesunate.

64. From November 26, 2016 to August 22, 2018, Respondent Park Compounding compounded at least 50,475 vials of human drug products with the bulk drug substance, artesunate, in the form of lyophilized powder, 60 mg injectable and other forms, including capsules and suppositories. Respondent Park Compounding then dispensed and sold at least 4,194 orders (1 to 123 vials per order) of human drug products made with the bulk drug substance, artesunate to patients, including those diagnosed with cancer.

65. When it compounded the human drug products described in paragraph 63, Respondent Park Compounding did not comply with the requirements of sections 501(a)(2)(b), 502(f)(1) and 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §353a) (Act). Namely, it did not receive approval for these human drug products from the FDA under new or abbreviated new drug applications, label these human drug products with adequate directions for use or follow current good manufacturing practices when compounding these human drug products.

66. Respondent Park Compounding's compounding of the human drug products did not qualify for an exemption from sections 501(a)(2)(b), 502(f)(1) and 505 of the Act, pursuant to section 503A of the Act, because the bulk drug substance, artesunate did not meet one of the following criteria: (1) it was not the subject of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph and the USP chapter on pharmacy compounding; (2) it was not a component of an FDA-approved human drug product; and (3) it did not appear on a list of bulk drug substances that may be used for compounding to be developed by the Secretary through regulation (503A bulks list) or appear on the 503A category 1 list as it had not been nominated for inclusion on the 503A bulks list.

67. From June 21, 2017 to April 10, 2018, Respondent Park Compounding also failed to perform USP Chapter 71 compliant sterility tests on 22 non-sterile to sterile batches of 28,859 vials of arestunate lyophilized powder 60 mg injectable.

/ / /

/ / /

68. From January 18, 2017 to December 24, 2017, Respondent Park Compounding failed to document the post-compounding process and procedures for at least 30,475 vials of artesunate lyophilized powder 60 mg injectable.

69. From January 3, 2017 to June 18, 2018, Respondent Park Compounding did not possess the required stability studies to support the assignment of a 180 day beyond use date for 43 batches of 47,731 vials of artesunate lyophilized powder 60 mg injectable.

70. From at least January 18, 2017 through June 6, 2017, Respondent Park Compounding dispensed 29 orders for 227 vials of artesunate lyophilized powder 60 mg injectable without labels specifying the dose and frequency of use.

71. Respondent Park Compounding made false statements to investors and in filings with Securities and Exchange Commission and communications with investors that artesunate was an active pharmaceutical ingredient (API) approved by the FDA. The bulk drug substance, artesunate is not an API approved by the FDA.

72. From at least on or around March 21, 2017 through May 24, 2018, Respondent Park Compounding falsely advertised the human drug products it compounded with the bulk drug substance, artesunate as being effective in treating cancer. When it dispensed drug products compounded with the bulk drug substance, artestunate to patients, it distributed an information leaflet claiming that artemisinin, i.e., artesunate has "an affinity for cancer cells and combines with the intercellular iron creating Reactive Oxygen Species (ROS) which leads to cancer cell death." Artesunate has not been proven to treat cancer in clinical drug trials on humans.

73. Respondent Park Compounding continued to compound human drug products with the bulk drug substance, artesunate even though the Board informed it that such compounding did not comply with federal and state law.

FIRST CAUSE FOR DISCIPLINE

(Manufactured, Sold, Delivered, Held or Offered for Sale Adulterated Drugs Against Park Compounding and ElGawly)

74. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code

section 111295 and Code section 4169, subdivision (a)(2), in that they manufactured, sold, delivered, held or offered for sale a compounded drug, curcumin emulsion that was adulterated within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Compounded Adulterated Drugs Against Park Compounding and ElGawly)

75. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111300, in that they compounded an adulterated drug, curcumin emulsion, within the meaning of Health and Safety Code sections 111250 and 111255, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Manufactured, Sold, Delivered, Held or Offered for Sale Misbranded Drugs Against Park Compounding and ElGawly)

76. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code sections 111440 and 111450 and Code section 4169, subdivision (a)(3), in that they manufactured, sold, delivered, held or offered for sale a compounded drug, curcumin emulsion that was misbranded within the meaning of Health and Safety Code section 111375, subdivision (c), as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Compounded Misbranded Drugs Against Park Compounding and ElGawly)

77. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111445, in that they compounded a misbranded drug, curcumin emulsion, within the meaning of Health and Safety Code section 111375, subdivision (c), as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

/ / /

FIFTH CAUSE FOR DISCIPLINE

(Dispensing Prescriptions with Significant Errors, Omissions, Irregularities, Uncertainties, Ambiguities or Alterations Against Park Compounding and ElGawly)

78. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (o), for violating title 16, California Code of Regulations, section 1761, subdivision (a), in that they dispensed prescriptions for curcumin emulsion, which contained significant errors, omissions, irregularities, uncertainties, ambiguities or alterations, in that they did not calibrate the dose by a patient's weight or consider a patient's allergies when filling and dispensing curcumin emulsion and dispensing 29 orders for 227 vials of artesunate lyophilized powder 60 mg injectable with no dose or frequency provided, as set forth in paragraphs 38 through 73 above, which are incorporated herein by reference.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Support Assigned Beyond Use Dates Against Park Compounding and ElGawly)

79. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (o), for violating title 16, California Code of Regulations, section 1735.2, subdivision (i)(3), and Code section 4169, subdivision (a)(4), in that they compounded curcumin emulsion, a sterile injectable drug and human drug products with artesunate and assigned beyond use dates which were not supported by method suitability tests, container closure integrity tests and/or stability studies, as set forth in paragraphs 38 through 73 above, which are incorporated herein by reference.

SEVENTH CAUSE FOR DISCIPLINE

(Gross Negligence Against Park Compounding and ElGawly)

80. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (c), for gross negligence for failing to voluntarily recall its compounded drug, curcumin emulsion and suspend its production of curcumin emulsion in a timely manner as required by their policies and procedures, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

/ / /

EIGHTH CAUSE FOR DISCIPLINE

(Transferred Dangerous Drugs to Unlicensed Entity Against Park Compounding and ElGawly)

81. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (o), for violating Code section 4169, subdivision (a)(1), in that they transferred dangerous drugs to an unlicensed entity, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

NINTH CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition and Disposition Against Park Compounding and ElGawly)

82. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (o), for violating Code sections 4081, subdivision (a), 4105, subdivision (a) and 4169, subdivision (a)(5), in that they failed to maintain all the records of acquisition and disposition, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

TENTH CAUSE FOR DISCIPLINE

(Subverting a Board Investigation Against Park Compounding)

83. Respondent Park Compounding is subject to disciplinary action under Code section 4301, subdivision (q), in that it failed to respond to requests for production of records repeatedly and misrepresented facts during the investigation, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

ELEVENTH CAUSE FOR DISCIPLINE

(Failure to Report Adverse Effects Against Park Compounding and ElGawly)

84. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivision (o), for violating Business and Professions Code section 4127.1, subdivision (f), in that they failed to report adverse effects or adverse effects potentially attributable to Park Compounding's sterile drug product, curcumin emulsion within 12 hours, as set forth in paragraphs 38 through 73 above, which are incorporated herein by reference.

TWELFTH CAUSE FOR DISCIPLINE

(Failure to Comply with Food, Drug and Cosmetic Act Against All Respondents)

85. Respondents are subject to disciplinary action under Code section 4301, subdivisions (o) and (j), for violating Food, Drug and Cosmetic Act, 21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and 355, in that they failed to obtain approval of drug products compounded with artesunate under new or abbreviated new drug applications, label drug products compounded with artesunate with adequate directions for use and adhere to current good manufacturing practices when compounding drug products with artesunate, as set forth in paragraphs 38 through 73 above, which are incorporated herein by reference.

THIRTEENTH CAUSE FOR DISCIPLINE

(Manufactured, Sold, Delivered, Held or Offered for Sale Misbranded Drugs Against All Respondents)

86. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 111425 and Code section 4169, subdivision (a)(3), in that they manufactured, sold, delivered, held or offered for sale drug products made with the bulk drug substance, artesunate, without having a valid license from the Department of Public Health, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

FOURTEENTH CAUSE FOR DISCIPLINE

(Disseminated False Public Communications Against All Respondents)

87. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Business and Professions Code section 651, in that they disseminated false public communications about artesunate, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

FIFTEENTH CAUSE FOR DISCIPLINE

(Disseminated False Advertisement of Drugs Against Park Compounding)

88. Respondent Park Compounding is subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating Health and Safety Code section 110390, in that it

disseminated false advertisements about artesunate, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

SIXTEENTH CAUSE FOR DISCIPLINE

(Dishonest, Deceitful and Fraudulent Acts Against All Respondents)

89. Respondents are subject to disciplinary action under Code section 4301, subdivision (f), in that they committed false, deceitful and fraudulent acts in that they filled thousands of orders for artesunate despite numerous violations of federal and state law regarding labeling, sterility, testing, and other violations, when they knew or should have known of such violations, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

SEVENTEENTH CAUSE FOR DISCIPLINE

(Failure to Complete Non-Sterile to Sterile End Product Testing Against Park Compounding, Desai, and Ibrahim)

90. Respondents Park Compounding, Ronak Desai, and Nadia Ibrahim are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1751.7, subdivision (e)(1), in that they failed to complete non-sterile to sterile end product testing on human drug products compounded with artesunate, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

EIGHTEENTH CAUSE FOR DISCIPLINE

(Failure to Document Post-Compounding Process and Procedures Against All Respondents)

91. Respondents are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1735.3, subdivision (a), in that they failed to document the required post-compounding process and procedures on at least thirty-one compounding logs for 30,475 vials of artesunate lyophilized powder 60 mg injectable, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

/ / /

/ / /

/ / /

/ / /

NINETEENTH CAUSE FOR DISCIPLINE

(Failure to Correctly Label Compounded Drug Preparations Against Park Compounding and ElGawly)

92. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1735.4, subdivision (a), in that they dispensed 29 orders for 227 vials of artesunate lyophilized powder 60 mg injectable with incomplete directions for use, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

TWENTIETH CAUSE FOR DISCIPLINE

(Failure to Correctly Label Compounded Drugs with Directions for Use Against Park Compounding and ElGawly)

93. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary action under Code section 4301, subdivisions (j) and (o), for violating California Code of Regulations, title 16, section 1735.4, subdivision (b), in that they dispensed 29 orders for 227 vials of artesunate lyophilized powder 60 mg injectable with incomplete directions for use, as set forth in paragraphs 38 through 73, which are incorporated herein by reference.

TWENTY-FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct Against All Respondents)

94. Respondents are subject to disciplinary action under Code section 4301 for unprofessional conduct in that they engaged in the activities described in paragraphs 38 through 73 above, which are incorporated herein by reference.

OTHER MATTERS

95. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 issued to Respondent Park Compounding. Respondent Park Compounding shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 are

placed on probation or until Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 are reinstated if they are revoked.

96. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 74911 issued to Respondent ElGawly, Respondent ElGawly 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 No. RPH 74911 is placed on probation or until Pharmacist License No. RPH 74911 is reinstated if it is revoked.

97. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 55103 issued to Respondent Ibrahim, Respondent Ibrahim 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 No. RPH 55103 is placed on probation or until Pharmacist License No. RPH 55103 is reinstated if it is revoked.

98. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License No. RPH 55481 issued to Respondent Desai, Respondent Desai 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 No. RPH 55481 is placed on probation or until Pharmacist License No. RPH 55481 is reinstated if it is revoked.

DISCIPLINARY CONSIDERATIONS

99. To determine the degree of discipline, if any, to be imposed on Respondent Park Compounding, Complainant alleges that:

a. On July 25, 2016, the Board issued Citation Nos. CI 2016 71269 and CI 2016 71270 to Respondent Park Compounding for violating Business and Professions Code sections 4110, subdivision (a) and 4127.1, subdivision (a), because it engaged in the practice of pharmacy and/or compounding without licenses. The Board issued fines that Respondent paid.

b. On April 26, 2017, the Board issued Citation No. CI 2015 68385 and CI 2016 74871 to Respondent Park Compounding for violating Health & Safety Code sections 111615, 111430 and 111440 and California Code of Regulations, title 16, section 1751.7, subdivision (b), because that Respondent manufactured and sold compounded drug preparations, and did not have a

validation process which was representative of all types of manipulations, products and batch sizes prior to compounding. The Board also issued the Citations against Respondent Park Compounding for violating California Code of Regulations, title 16, section 1761, subdivision (a), for dispensing drugs without directions for use. The Board issued fines that Respondent paid.

c. On March 29, 2018, the Board issued Citation number CI 2017 77032 to Respondent Park Compounding, Inc. for violating California Code of Regulations, title 16, sections 1735.2, subdivision (e), 1735.3, subdivision (a) and 1735.4, subdivision (a), because that Respondent compounded drugs without preparing a written master formula with all required elements, compounded drugs without completing a compounding log and dispensed compounded drugs with labels that lacked the date compounded and the lot number or pharmacy reference number. The Board issued fines that Respondent paid.

d. On March 29, 2018, the Board issued Citation No. CI 2017 79201 to Respondent ElGawly for violating California Code of Regulations, title 16, sections 1735.2, subdivision (e), 1735.3, subdivision (a) and 1735.4, subdivision (a), because that Respondent compounded drugs without preparing a written master formula with all required elements, compounded drugs without completing a compounding log and dispensed compounded drugs with labels that lacked the date compounded and the lot number or pharmacy reference number. The Board issued a fine that Respondent paid.

e. On July 25, 2016, the Board issued Citation No. CI 2016 71268 to Respondent Ibrahim for violating for violating Business and Professions Code sections 4110, subdivision (a) and 4127.1, subdivision (a), because she engaged in the practice of pharmacy and/or compounding without licenses.

f. On April 26, 2017, the Board issued Citation No. CI 2016 74872 to Respondent ElGawly for violating Health & Safety Code sections 111615, 111430 and 111440 and California Code of Regulations, title 16, section 1751.7, subdivision (b), because that Respondent manufactured and sold compounded drug preparations, and did not have a validation process which was representative of all types of manipulations, products and batch sizes prior to compounding. The Board issued fines that Respondent paid.

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 53360, issued to Respondent Park Compounding, Inc., doing business as Park Compounding;

2. Revoking or suspending Sterile Compounding Permit Number LSC 100771, issued to Respondent Park Compounding, Inc., doing business as Park Compounding;

3. Revoking or suspending Pharmacist License Number RPH 74911, issued to Respondent Mariam Saad Fouad Bekhit ElGawly;

4. Revoking or suspending Pharmacist License Number RPH 55103, issued to Respondent Nadia Mohamed Elsayed Ibrahim;

5. Revoking or suspending Pharmacist License Number RPH 55481, issued to Respondent Ronak A. Desai;

6. Prohibiting Respondent Park Compounding, Inc., doing business as Park Compounding from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 are placed on probation or until Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 are reinstated if Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 issued to Park Compounding, Inc., doing business as Park Compounding are revoked;

7. Prohibiting Respondent Mariam Saad Fouad Bekhit ElGawly from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License No. RPH 74911 is placed on probation or until Pharmacist License No. RPH 74011 is reinstated if Pharmacist License No. RPH 74911 issued to Respondent Mariam Saad Fouad Bekhit ElGawly is revoked;

8. Prohibiting Respondent Nadia Mohamed Elsayed Ibrahim from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License No. RPH 55103 is placed on probation or until Pharmacist License

No. RPH 55103 is reinstated if Pharmacist License No. RPH 55103 issued to Respondent Nadia Mohamed Elsayed Ibrahim is revoked;

9. Prohibiting Respondent Ronak A. Desai from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Pharmacist License No. RPH 55481 is placed on probation or until Pharmacist License No. RPH 55481 is reinstated if Pharmacist License No. RPH 55481 issued to Respondent Ronak A. Desai is revoked;

10. Ordering Respondent Park Compounding, Inc., doing business as Park Compounding, Mariam Saad Fouad Bekhit ElGawly, Mariam Saad Fouad Bekhit ElGawly and Ronak A. Desai 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,

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

DATED: November 7, 2019

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

SD2017802233/82203584.docx