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9 **BEFORE THE**
BOARD OF PHARMACY
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 6271

13 **PARK COMPOUNDING INC.**
14 **DBA PARK COMPOUNDING**
15 **F.K.A. IMPRIMISRX**
9257 Research Drive
Irvine, CA 92618

SECOND AMENDED ACCUSATION

16 **Pharmacy Permit No. PHY 53360**

17 **Sterile Compounding License No. LSC 100771**

18 **MARIAM SAAD FOUAD BEKHIT**
19 **ELGAWLY**
652 Marketview
20 Irvine, CA 92602

21 **Pharmacist License No. RPH 74911**

22 **NADIA MOHAMED ELSAYED IBRAHIM**
162 Calle De Los Ninos
23 Rancho Santa Margarita, CA 92688

24 **Pharmacist License No. RPH 55103**

25 **RONAK AMIT DESAI**
16611 Maurice Circle
26 Cerritos, CA 90703

27 **Pharmacist License No. RPH 55481**

28 Respondents.

1 Complainant alleges:

2 **PARTIES**

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

6 2. On or about August 26, 2015, the Board issued Pharmacy Permit Number PHY
7 53360 to Imprimis Pharmaceuticals, Inc. and South Coast Specialty Compounding, Inc., doing
8 business as Park Compounding. On June 1, 2016, South Coast Specialty Compounding, Inc.
9 became known as Imprimis Pharmaceuticals, Inc., doing business as ImprimisRx (Respondent
10 Park Compounding¹). On November 7, 2017, ImprimisRx became known as Park Compounding,
11 Inc., doing business as Park Compounding. The Pharmacy Permit was in full force and effect at
12 all times relevant to the charges brought herein and will expire on August 1, 2019, unless
13 renewed.

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

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

25 5. On or about September 16, 2003, the Board issued Pharmacist License Number RPH
26 55103 to Nadia Mohamed Elsayed Ibrahim (Respondent Ibrahim). The Pharmacist License was

27 _____
28 ¹ Though the facility changed names at different times relevant to this Accusation,
Respondent facility is referenced at all times herein as “Park Compounding.”

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

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

7 **JURISDICTION**

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

11 8. Section 4011 of the Code provides that the Board shall administer and enforce both
12 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
13 Act [Health & Safety Code, § 11000 et seq.].

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

16 10. Section 4300.1 of the Code states:

17 The expiration, cancellation, forfeiture, or suspension of a board-issued license
18 by operation of law or by order or decision of the board or a court of law, the
19 placement of a license on a retired status, or the voluntary surrender of a license by a
20 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.

21 **STATUTORY AND REGULATORY PROVISIONS**

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

23 (a) It is unlawful for any person licensed under this division or under any
24 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
25 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
26 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,
27 communication by means of mail, television, radio, motion picture, newspaper, book,
list or directory of healing arts practitioners, Internet, or other electronic
28 communication.

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

3 (1) Contains a misrepresentation of fact.

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

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

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

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

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

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

28 (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

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

3 (d) Any person so licensed shall not compensate or give anything of value to a
4 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.

5 (e) Any person so licensed may not use any professional card, professional
6 announcement card, office sign, letterhead, telephone directory listing, medical list,
7 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).

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

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

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

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

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

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

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

18 (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
19 fields.

20 (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
21 certified or eligible for certification by a private or public board or parent association
recognized by that practitioner's licensing board.

22 (C) A physician and surgeon licensed under Chapter 5 (commencing with
23 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
24 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,
25 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
26 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
27 approved postgraduate training program that provides complete training in that
specialty or subspecialty. A physician and surgeon licensed under Chapter 5
28 (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

1 (iii) shall not use the term “board certified” in reference to that certification, unless
2 the physician and surgeon is also licensed under Chapter 4 (commencing with Section
3 1600) and the use of the term “board certified” in reference to that certification is in
4 accordance with subparagraph (A). A physician and surgeon licensed under Chapter 5
5 (commencing with Section 2000) by the Medical Board of California who is certified
6 by a board or association referred to in clause (i), (ii), or (iii) shall not use the term
7 “board certified” unless the full name of the certifying board is also used and given
8 comparable prominence with the term “board certified” in the statement.

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

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

22 (D) A doctor of podiatric medicine licensed under Article 22 (commencing with
23 Section 2460) of Chapter 5 by the California Board of Podiatric Medicine may
24 include a statement that he or she is certified or eligible or qualified for certification
25 by a private or public board or parent association, including, but not limited to, a
26 multidisciplinary board or association, if that board or association meets one of the
27 following requirements: (i) is approved by the Council on Podiatric Medical
28 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.

1 The California Board of Podiatric Medicine shall adopt regulations to establish
2 and collect a reasonable fee from each board or association applying for recognition
3 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.

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

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

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

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

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

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

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

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

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

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

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

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

28 (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

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

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

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

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

26 (a) All records of manufacture and of sale, acquisition, or disposition of
27 dangerous drugs or dangerous devices shall be at all times during business hours open
28 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.

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

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

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

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

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

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

14 (3) Purchase, trade, sell or transfer dangerous drugs that the person knew or
15 reasonably should have known were misbranded, as defined in Section 111335 of the
16 Health and Safety Code.

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

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

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

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

25 ...

26 (c) Gross negligence.

27 ...

28 (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.

1 ...

2 (o) Violating or attempting to violate, directly or indirectly, or assisting in or
3 abetting the violation of or conspiring to violate any provision or term of this chapter
4 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.

5 ...

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

8 ...

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

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

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

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

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

16 Any person who has been denied a license or whose license has been revoked
17 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,
18 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
19 has been placed on probation, and while acting as the manger, administrator, owner,
member, officer, director, associate, or partner had knowledge or knowingly
20 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:

21
22 (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
23 years.

24 (2) Where the license is denied or revoked, the prohibition shall continue until
the license is issued or reinstated.

25
26 19. Health and Safety Code section 110390 states:

27 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
28 in any particular.

1 20. Health and Safety Code section 111250 states:

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

4 21. Health and Safety Code section 111255 states:

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

8 22. Health and Safety Code section 111295 states:

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

11 23. Health and Safety Code section 111300 states:

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

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

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

18 25. Health and Safety Code section 111440 states:

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

21 26. Health and Safety Code section 111425 states:

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

24 27. Health and Safety Code section 111445 states:

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

26 28. Health and Safety Code section 111450 states:

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

///

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

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

7 Extension of a beyond use date is only allowable when supported by the
8 following: (A) Method Suitability Test, (B) Container Closure Integrity Test, and (C)
9 Stability Studies.

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

11 For each compounded drug preparation, pharmacy records shall include:

12 (1) The master formula document.

13 (2) A compounding log consisting of a single document containing all of the
14 following:

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

16 (B) The date the drug preparation was compounded.

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

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

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

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

26 (i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile
27 preparations compounded in a single lot for administration within seventy-two (72)
28 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.

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

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

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

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

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

12 (3) Instructions for storage, handling, and administration. For admixed IV
13 solutions, the rate of infusion shall be included;

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

15 (5) The date compounded; and

16 (6) The lot number or pharmacy reference number.

17 (b) Any compounded drug preparation dispensed to a patient or readied for
18 dispensing to a patient shall also include on the label the information required under
19 Business and Professions Code section 4076 and California Code of Regulations, title
20 16, section 1707.5.

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

22 Batched-produced sterile drug preparations compounded from one or more non-
23 sterile ingredients, except as provided in paragraph (2), shall be subject to
24 documented end product testing for sterility and pyrogens and shall be quarantined
25 until the end product testing confirms sterility and acceptable levels of pyrogens.
26 Sterility testing shall be USP Chapter 71 compliant and pyrogens testing shall
27 confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing.
28 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 licensee 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

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

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

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

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

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

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

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

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

1 50. On March 17, 2017, Respondent Park Compounding reported J.E.'s adverse effects to
2 the curcumin emulsion to the Board even though it learned of those adverse effects on March 13,
3 2017. Respondent Park Compounding did not voluntarily recall its curcumin emulsion within
4 expiry nor suspend the compounding of curcumin emulsion.

5 51. On March 20, 2017, the FDA issued a warning letter to Respondent Park
6 Compounding based on the FDA's inspections, noting "serious deficiencies in [Respondent Park
7 Compounding's] practices for producing sterile drug products, which put patients at risk" and the
8 issuance of a Form FDA 483 to Respondent Park Compounding on March 14, 2016.² The FDA
9 concluded that Respondent Park Compounding appeared to produce drug products that violated
10 the Federal Food, Drug and Cosmetic Act, including the production of adulterated drug products.
11 (FDA noted that "drug products intended or expected to be sterile were prepared, packed, or held
12 under insanitary conditions, whereby they may have become contaminated with filth or rendered
13 injurious to health causing [Respondent Park Compounding's] drug products to be adulterated
14 under section 501(a)(2)(A) of the FDCA"). The FDA strongly recommended that Respondent
15 Park Compounding's management "undertake a comprehensive assessment of operations,
16 including facility design, procedures, personnel, processes, maintenance, materials, and systems.
17 In particular, this review should assess your aseptic processing operations."

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

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

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

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

4 55. On May 8, 2017, Respondent Park Compounding reported W.K.'s adverse effects to
5 the curcumin emulsion to the Board even though it learned of W.K.'s adverse effects on May 4,
6 2017. Respondent Park Compounding did not voluntarily recall its curcumin emulsion within
7 expiry or suspend the compounding or dispensing of curcumin emulsion.

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

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

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

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

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

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

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

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

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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 artesunate lyophilized powder 60 mg injectable.

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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, artesunate 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

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

5 **SECOND CAUSE FOR DISCIPLINE**

6 **(Compounded Adulterated Drugs Against Park Compounding and ElGawly)**

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

12 **THIRD CAUSE FOR DISCIPLINE**

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

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

21 **FOURTH CAUSE FOR DISCIPLINE**

22 **(Compounded Misbranded Drugs Against Park Compounding and ElGawly)**

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

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1 **FIFTH CAUSE FOR DISCIPLINE**

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

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

12 **SIXTH CAUSE FOR DISCIPLINE**

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

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

21 **SEVENTH CAUSE FOR DISCIPLINE**

22 **(Gross Negligence Against Park Compounding and ElGawly)**

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

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1 **EIGHTH CAUSE FOR DISCIPLINE**

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

4 81. Respondents Park Compounding and Mariam ElGawly are subject to disciplinary
5 action under Code section 4301, subdivision (o), for violating Code section 4169, subdivision
6 (a)(1), in that they transferred dangerous drugs to an unlicensed entity, as set forth in paragraphs
7 38 through 73, which are incorporated herein by reference.

8 **NINTH CAUSE FOR DISCIPLINE**

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

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

16 **TENTH CAUSE FOR DISCIPLINE**

17 **(Subverting a Board Investigation Against Park Compounding)**

18 83. Respondent Park Compounding is subject to disciplinary action under Code section
19 4301, subdivision (q), in that it failed to respond to requests for production of records repeatedly
20 and misrepresented facts during the investigation, as set forth in paragraphs 38 through 73, which
21 are incorporated herein by reference.

22 **ELEVENTH CAUSE FOR DISCIPLINE**

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

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

1 **TWELFTH CAUSE FOR DISCIPLINE**

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

3 85. Respondents are subject to disciplinary action under Code section 4301, subdivisions
4 (o) and (j), for violating Food, Drug and Cosmetic Act, 21 U.S.C. §§ 351(a)(2)(B), 352(f)(1), and
5 355, in that they failed to obtain approval of drug products compounded with artesunate under
6 new or abbreviated new drug applications, label drug products compounded with artesunate with
7 adequate directions for use and adhere to current good manufacturing practices when
8 compounding drug products with artesunate, as set forth in paragraphs 38 through 73 above,
9 which are incorporated herein by reference.

10 **THIRTEENTH CAUSE FOR DISCIPLINE**

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

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

19 **FOURTEENTH CAUSE FOR DISCIPLINE**

20 **(Disseminated False Public Communications Against All Respondents)**

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

25 **FIFTEENTH CAUSE FOR DISCIPLINE**

26 **(Disseminated False Advertisement of Drugs Against Park Compounding)**

27 88. Respondent Park Compounding is subject to disciplinary action under Code section
28 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.

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1 **NINETEENTH CAUSE FOR DISCIPLINE**

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

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

9 **TWENTIETH CAUSE FOR DISCIPLINE**

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

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

17 **TWENTY-FIRST CAUSE FOR DISCIPLINE**

18 **(Unprofessional Conduct Against All Respondents)**

19 94. Respondents are subject to disciplinary action under Code section 4301 for
20 unprofessional conduct in that they engaged in the activities described in paragraphs 38 through
21 73 above, which are incorporated herein by reference.

22 **OTHER MATTERS**

23 95. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit
24 No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 issued to Respondent Park
25 Compounding. Respondent Park Compounding shall be prohibited from serving as a manager,
26 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
27 Pharmacy Permit No. PHY 53360 and/or Sterile Compounding Permit No. LSC 100771 are
28

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

3 96. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
4 No. RPH 74911 issued to Respondent ElGawly, Respondent ElGawly shall be prohibited from
5 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
6 licensee for five years if Pharmacist License No. RPH 74911 is placed on probation or until
7 Pharmacist License No. RPH 74911 is reinstated if it is revoked.

8 97. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
9 No. RPH 55103 issued to Respondent Ibrahim, Respondent Ibrahim shall be prohibited from
10 serving as a manager, administrator, owner, member, officer, director, associate, or partner of a
11 licensee for five years if Pharmacist License No. RPH 55103 is placed on probation or until
12 Pharmacist License No. RPH 55103 is reinstated if it is revoked.

13 98. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License
14 No. RPH 55481 issued to Respondent Desai, Respondent Desai shall be prohibited from serving
15 as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee
16 for five years if Pharmacist License No. RPH 55481 is placed on probation or until Pharmacist
17 License No. RPH 55481 is reinstated if it is revoked.

18 **DISCIPLINARY CONSIDERATIONS**

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

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

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

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

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

12 d. On March 29, 2018, the Board issued Citation No. CI 2017 79201 to Respondent
13 ElGawly for violating California Code of Regulations, title 16, sections 1735.2, subdivision (e),
14 1735.3, subdivision (a) and 1735.4, subdivision (a), because that Respondent compounded drugs
15 without preparing a written master formula with all required elements, compounded drugs
16 without completing a compounding log and dispensed compounded drugs with labels that lacked
17 the date compounded and the lot number or pharmacy reference number. The Board issued a fine
18 that Respondent paid.

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

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

1 **PRAYER**

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

4 1. Revoking or suspending Pharmacy Permit Number PHY 53360, issued to Respondent
5 Park Compounding, Inc., doing business as Park Compounding;

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

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

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

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

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

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

26 8. Prohibiting Respondent Nadia Mohamed Elsayed Ibrahim from serving as a manager,
27 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
28 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

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