IN THE MATTER OF	*	**BEFORE THE**
PARK COMPOUNDING, INC.	*	**MARYLAND BOARD**
RESPONDENT	*	**OF PHARMACY**
PERMIT NO.: P07392	*	**Case No.: 19-380**

* * * * * * * * * * * * *

FINAL ORDER OF REVOCATION OF PHARMACY PERMIT

The Maryland Board of Pharmacy (the "Board") hereby revokes **PARK COMPOUNDING, INC.'s, Permit Number P07392** (the "Respondent-Pharmacy"), permit to operate a pharmacy, pursuant to the Maryland Pharmacy Act (the "Act"), Md. Code Ann., Health Occ. §§ 12-101 *et seq.* (2014 Repl. Vol. and 2019 Supp.).

The pertinent provisions of the Act are as follows:

§ 12-409. Suspension or revocation of permit

(a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(1) Is conducted so as to endanger the public health or safety;

(2) Violates any of the standards specified in § 12-403 of this subtitle; or

(3) Otherwise is not conducted in accordance with the law.

(b)

(1) A nonresident pharmacy is subject to the disciplinary actions stated in this subtitle.

(2) The Board may fine a nonresident pharmacy in accordance with § 12-410 of the subtitle or deny, revoke, or suspend the permit of a nonresident pharmacy for any violation of § 12-403(e) through (h) of this subtitle.

§ 12-403. Nonresident Pharmacies; rules and regulations

. . . .

(c) Except as otherwise provided in this section, a pharmacy for which a permit has been issued under this title:

. . . .

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 of this title, a registered pharmacy technician under § 12-6B-09 of this title, or a registered pharmacy intern under § 12-6D-11 of this title[.]

. . . .

(g) Notwithstanding subsection (b) of this section, a nonresident pharmacy shall:

(1) Comply with the requirements of subsection (c)(2), (7) through (12), and (19) of this section when:

(i) Dispensing prescriptions drugs or prescriptions devices to a patient in this State; or

(ii) Otherwise engaging in the practice of pharmacy in this State[.]

Health Occ. § 12-313. Denials, reprimands, suspensions, and revocations - Grounds.

. . . .

(b) Subject to the hearing provisions of § 12–315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a license to any applicant for a pharmacist's license, reprimand any licensee, place any licensee on probation, or suspend or revoke a license of a pharmacist if the applicant or licensee:

. . . .

(17) Violates any provision of § 12-505 of this title, which concerns the labeling requirements for prescriptions for drugs, devices, or diagnostics;

. . . .

(20) Advertises in a manner that tends to deceive or defraud the public;

(21) Is professionally, physically, or mentally incompetent;

. . . .

(24) Is disciplined by a licensing or disciplinary authority of any state or country or convicted or disciplined by a court of any state or country for an act that would be grounds for disciplinary action under the Board's disciplinary statute;

(25) Violates any rule or regulation adopted by the Board[.]

§12-505. Labeling Regulations, Generally.

(d) (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device[.]

The pertinent provisions of Code Md. Regs ("COMAR"), 10.34 *et seq.* provide as follows:

COMAR 10.34.10.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the practice of pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

(a) United States Code, Title 21,

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code of Maryland[.]

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

(2) Practice pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment, or

(3) Engage in unprofessional conduct.

COMAR 10.34.10.04 Competence.

A pharmacy technician, pharmacy intern or a pharmacist shall:

A. Maintain knowledge of the current pharmacy and drug laws and health and sanitation laws relevant to the practice of pharmacy; and

B. Provide a pharmaceutical service only with the scope of the pharmacy technician's, pharmacy intern's or pharmacist's training and education.

COMAR 10.34.19.04 Pharmacy Environment.

The compounding, preparation, and dispensing of compounded sterile preparations shall be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards.

COMAR 10.34.19.05 General Requirements.

A licensed pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy shall control and supervise the section of the pharmacy that prepares compounded sterile preparations and is responsible for, at a minimum, the following;

. . . .

C. Labeling of containers of compounded sterile preparations compound within the pharmacy[.]

FINDINGS OF FACT

The Board finds:

1. The Respondent-Pharmacy was initially issued a permit to operate as an out-of-state pharmacy in the state of Maryland on or about October 21, 2016. The Respondent-Pharmacy's permit expired on May 31, 2020. The Respondent-Pharmacy closed on August 28, 2019.

2. On or about May 17, 2019, the Board received a letter from the Respondent-Pharmacy informing the Board that the California Board of Pharmacy issued a disciplinary order against the Respondent-Pharmacy. Additionally, the Respondent-Pharmacy also informed the Board that the Respondent-Pharmacy entered into a Stipulated Surrender of License and Order with the California Board of Pharmacy.

California Discipline

3. The Respondent-Pharmacy was originally issued a license to operate as a pharmacy in the State of California on or about August 26, 2015. The Respondent-Pharmacy license expired on August 1, 2020. On or about May 29, 2019, the Respondent-Pharmacy surrendered their California license.

4. On or about August 26, 2015, the California Board issued a Pharmacy Permit 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, Inc.

5. On or about April 29, 2019, the Board of Pharmacy Department of Consumer Affairs State of California ("California Board") issued a Stipulated Surrender of License and Order ("2019 Disciplinary Order")[1] against the Respondent-Pharmacy's license. The California Board ordered the Respondent-Pharmacy to surrender their license.

6. The Respondent-Pharmacy was disciplined because the Respondent-Pharmacy:

a. manufactured, sold, delivered, held, or offered for sale a compounded drug, curcumin emulsion that was adulterated;

b. compounded an adulterated drug, curcumin emulsion;

c. manufactured, sold, delivered, held, or offered for sale a compounded drug, curcumin emulsion that was misbranded;

d. compounded a misbranded drug, curcumin emulsion;

e. dispensed prescriptions for curcumin emulsion, which contained significant errors, omissions, irregularities, uncertainties, ambiguities, or alterations;

f. failed to calibrate medication dosage by a patient's weight or consider a patient's allergies when filling and dispensing curcumin emulsion and

[1] For confidentiality and privacy purposes, the names of individuals and facilities involved in this case are not disclosed in this document. Upon written request, the Administrative Prosecutor will provide the information to the Respondent-Pharmacy.

dispensing 29 orders for 227 vials of artesunate lyophilized powder 60mg injectable with no dose or frequency provided;

g. 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;

h. transferred dangerous drugs to an unlicensed entity;

failed to maintain all the records of acquisition and disposition;

i. 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;

j. 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;

k. disseminated false public communications and false advertisements about artesunate;

l. committed false, deceitful, and fraudulent acts when the Respondent-Pharmacy made representations about artesunate;

m. failed to complete non-sterile to sterile end product testing on human drug products compounded with artesunate;

n. failed to document the required post-compounding process and procedures on at least thirty-one (31) compounding logs for 30,475 vials of artesunate lyophilized powder 60mg injectable;

o. dispensed twenty-nine (29) orders for 227 vials of artesunate lyophilized powder 60mg injectable with incomplete directions for use;

p. engaged in unprofessional conduct as a pharmacy.

7. In the 2019 Disciplinary Order, the California Board made the following Factual Allegations:

. . . .

> 37. . . . [The Respondent-Pharmacy] compounded and dispensed sterile injectable drug preparations and other human drug products. [The Respondent-Pharmacy] is not a registered "503A outsourcer" with the Federal Drug Administration (FDA) nor does it hold a valid license with the California State Department of Public Health.

. . . .

> 40. From January 13, 2017 through June 15, 2017, Respondent-Pharmacy compounded a sterile injectable drug preparation, curcumin emulsion. Respondent-Pharmacy compounded that drug preparation with an excipient, PEG 40 castor oil (No. P2404). The PEG 40 castor oil used by Respondent-Pharmacy contained higher than allowable 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-Pharmacy 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 label." The

Toxicological information section noted that "ingestion . . . PEG may be a human allergen or hapten. Anaphylaxis may occur following ingestion of PEG."

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

42. From January 13, 2017 through June 15, 2017, Respondent-Pharmacy 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 Respondent-Pharmacy failed to even record patients' weight, let alone calibrate the doses accordingly.

43. From January 9, 2017, through April 14, 2017, Respondent-Pharmacy dispensed curcumin emulsion without labels warning about hypersensitivities reactions associated with PEG 40 castor oil (No. P2404).

44. On February 8, 2017, Respondent-Pharmacy dispensed curcumin emulsion to the wife of a naturopathic physician K.K.

45. On March 10, 2017, Dr. K.K. administered that curcumin emulsion compounded by Respondent-Pharmacy 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.

46. The vial of curcumin emulsion compounded by [Respondent-Pharmacy] and administered to patient J.E., and the lots from which that vial was derived, contained higher than allowable levels (i.e., greater than 0.1%) of DEG.

47. On March 16, 2017, Respondent-Pharmacy dispensed curcumin emulsion to a naturopathic nurse practitioner S.G.

48. On March 17, 2017, [the Respondent-Pharmacy] reported J.E.'s adverse effects to the curcumin emulsion to the [California Board] even though it learned those adverse

effects on March 13, 2017. [The Respondent-Pharmacy] did not voluntarily recall its curcumin emulsion within expiry nor suspend the compounding of curcumin emulsion.

49. On March 20, 2017, the Food and Drug Administration (FDA) issued a warning letter to [Respondent-Pharmacy] based on the FDA's inspections, noting 'serious deficiencies in [Respondent-Pharmacy's] practices for producing sterile drug products, which put patients at risk" and the issuance of a Form FDA 483 to [Respondent-Pharmacy] on March 14, 2016. The FDA concluded that [Respondent-Pharmacy] 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-Pharmacy] drug products to be adulterated under section 501(a)(2)(A) of the FDCA."). The FDA strongly recommended that [the Respondent-Pharmacy'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 operations."

. . . .

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

52. On April 10-12, 2017, Respondent-Pharmacy transferred dangerous drugs to a facility which was not licensed by the [California Board] and located in New Jersey.

53. On or about May 4, 2017, Nurse Practitioner S.G. administered curcumin emulsion compounded by

Respondent-Pharmacy to a patient, W.K. who was subsequently admitted to an emergency room of a hospital with an anaphylactic reaction.

54. On May 8, 2017, [the Respondent-Pharmacy] reported W.K.'s adverse effects to the curcumin emulsion to the [California Board] even though it learned of W.K.'s adverse effects on May 4, 2017. [The Respondent-Pharmacy] did not voluntarily recall its curcumin emulsion within expiry or suspend the compounding or dispensing of curcumin emulsion.

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

56. On June 1, 2017, the FDA requested [Respondent-Pharmacy] voluntarily recall curcumin emulsion containing PEG 40 castor oil and informed [Respondent-Pharmacy] that the DEG in the PEG 40 castor oil (No. P2404) exceeded allowable limits. [The Respondent-Pharmacy] refused to do so but did suspend the compounding and dispensing of curcumin emulsion. [The Respondent-Pharmacy] requested that its wholesaler perform testing to determine the potency of DEG 40 castor oil (No. P2402) use by [the Respondent-Pharmacy].

57. On June 15, 2017, the FDA requested again that [the Respondent-Pharmacy] voluntarily recall the curcumin emulsion compounded by it, but [the Respondent-Pharmacy] refused to do so.

58. On June 19, 2017, after [the Respondent-Pharmacy] was told twice by the FDA and the Board that [the Respondent-Pharmacy's] curcumin emulsion did not met specifications and presented a risk to patients, [the Respondent-Pharmacy] recalled its curcumin emulsion containing PEG 40 castor oil (No. P24404) within expiry. In its recall notice, [Respondent-Pharmacy] stated that it was recalling all affected lots of curcumin emulsion because the FDA notified [the Respondent-Pharmacy] that "one of its suppliers mislabeled

an inactive ingredient contained in small quantities in the [affected] lots" of curcumin emulsion.

59. On August 4, 2017, the FDA released a MedWatch which stated, in pertinent part, "FDA's investigation into the adverse events associated with [the Respondent-Pharmacy'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 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 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."

60. On August 7, 2017, [Respondent-Pharmacy] 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.

61. On August 22, 2017, and in response to the [California Board's] inquiry, [the Respondent-Pharmacy] 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 [the Respondent Pharmacy's] curcumin emulsion and determined that the DEG levels in the excipient, PEG 40 castor oil (No. P2404) were actually above the allowable 0.1% limit.

62. Despite receiving five requests from the [California Board], [the Respondent-Pharmacy] failed to produce all records requested by the [California Board], including prescriptions. [The Respondent-Pharmacy's] dispensing records were incomplete including prescriptions which did not list the pharmacist who dispensed curcumin emulsion.

63. From November 26, 2016 to August 22, 2018, [Respondent-Pharmacy] compounded at least 50,475 vials of human drug products with bulk drug substances, artesunate, in the form of lyophilized powder, 60mg injectable and other forms, including capsules and suppositories. [Respondent-Pharmacy] 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.

64. When it compounded the human drug products described in paragraph 63, [the Respondent-Pharmacy] 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 with adequate directions for use or follow current good manufacturing practices when compounding these drug products.

65. [Respondent-Pharmacy's] compounding of the human drug products described in paragraph 63, did not qualify for an exemption from sections 501(a)(2)(b), 502(f)(1) and 505 0f the Act, pursuant to sections 503A of the Act, because the bulk drug substances, 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) manograph 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 regulations (503A bulks list) or appear on the 503A category 1 list as it had not been nominated for inclusion on the 503A bulks list.

66. From June 21, 2017 to April 10, 2018, [Respondent-Pharmacy] also failed to perform USP Chapter 71 compliant sterility tests on 22 non-sterile batches of 28,859 vials of artesunate lyophilized powder 60mg injectable.

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

68. From January 3, 2017, to June 18, 2018, [Respondent-Pharmacy] 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 60mg injectable.

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

70. [The Respondent-Pharmacy] made false statements to investors and in fillings 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.

71. [The Respondent-Pharmacy] 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 teat cancer in clinical drug trials on humans.

72. [The Respondent-Pharmacy] continued to compound human drug products with bulk drug substance, artesunate even though the [California Board] informed it that such compounding did not comply with federal and state law.

8. The Respondent-Pharmacy's conduct as set forth above, constitutes a violation of Health Occ. §12-409(a)(1), (2), and (3); Health Occ. §12-409(b)(1) and (2); Health Occ. §12-403(c)(9)(g)(1)(i) and (ii); Health Occ. §12-313(b)(17), (20), (21), (24), and (25); Health Occ. §12-505(d)(2)(i); COMAR 10.34.10.01A(1)(a), (b), and (c); and B (1), (2),

and (3); COMAR 10.34.10.04A, and B; COMAR l0.34.19.04; and COMAR 10.34.19.05C.

CONCLUSIONS OF LAW

The Board concludes that the Respondent-Pharmacy violated Health Occ. §12-409(a)(l), (2), and (3); Health Occ. §12-409(b)(l) and (2); Health Occ. §12-403(c)(9)(g)(l)(i) and (ii); Health Occ. § 12-313(b)(17), (20), (21), (24), and (25); Health Occ. §12-505(d)(2)(i); COMAR 10.34.10.0lA(l)(a), (b), and (c); and B (1), (2), and (3); COMAR 10.34.10.04A, and B; COMARl0.34.19.04; and COMAR 10.34.19.05C.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, a majority of a quorum of the Board hereby:

ORDERED that the Respondent-Pharmacy's permit to operate as a pharmacy in the State of Maryland is hereby **REVOKED;** and it is further

ORDERED that the owners of Respondent-Pharmacy shall return to the Board all Maryland permits within ten (10) days of the date of this Order; and it is further

ORDERED that the effective date of this Order is the date that it is signed by the Board; and it is further

ORDERED that this Order is reportable to the National Practitioner Data Bank; and it is further

ORDERED that this document constitutes a formal disciplinary action of the Board of Pharmacy and is a public document for purposes of public disclosure, pursuant

to Md. Code Ann., General Provisions §§ 4-101 *et seq.* (2014 Repl. Vol and 2019 Supp.).

NOTICE OF RIGHT OF APPEAL

In accordance with § 12-316 of the Act and Md. Code Ann., State Government §§ 10-201, *et seq.* (2014 Repl. Vol. and 2019 Supp.), you have a right to a direct judicial appeal of this decision. A petition for appeal of the Final Board Order shall be filed within thirty days from your receipt of this Final Order and shall be made in accordance with the aforecited authority.

2-23-21
Date

Deena Speights Napata
Deena Speights Napata, M.A.
Executive Director for
Kevin Morgan, Pharm.D.
President
Maryland Board of Pharmacy