

IN THE MATTER OF * **BEFORE THE**
KEY COMPOUNDING PHARMACY * **MARYLAND STATE**
PERMIT NO. P04568 * **BOARD OF PHARMACY**
* **Case No. 19-067**

* * * * *

PRE-CHARGE CONSENT ORDER

Background

In August 17, 2018, the Maryland Board of Pharmacy (the “Board”) received a self-report from Key Compounding Pharmacy (the “Pharmacy”) that it had entered into a Settlement Agreement with the Missouri Board of Pharmacy based on an FDA 483 issued in March 2017 that indicated certain sterile compounding issues, including actionable environmental contamination. The Pharmacy subsequently issued a limited voluntary recall of products compounded during the affected time period, including one product dispensed to a Maryland patient. The FDA issued a Warning letter on April 4, 2018 regarding remaining issues stemming from the March 2017 FDA 483. The Pharmacy failed to report the adverse events to the Board as required.

In lieu of instituting formal proceedings against Key Compounding Pharmacy and in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Key Compounding Pharmacy, Inc., have agreed to resolve this matter as set forth in this Pre-Charge Consent Order. It is further agreed and understood that this Order constitutes a non-disciplinary disposition.

FINDINGS OF FACT

1. Key Compounding Pharmacy is a pharmacy located in Federal Way, Washington,

holding Non-Resident Pharmacy Permit Number P04568.

2. In March 2017, the FDA conducted inspections of the Pharmacy's sterile compounding operations. As a result, the FDA issued an FDA Form 483 list of observations that cited various USP 797 violations to include environmental contamination, poor aseptic technique, and cleaning deficiencies.
3. As a result, the Pharmacy initiated a voluntary recall of certain drug products compounded between November 2016 and February 2017. One (1) Maryland patient had been dispensed a sterile drug product subject to the recall. The Pharmacy communicated with the patient and the prescriber regarding the recall.
4. The Pharmacy failed to file an Adverse Event Report with the Board within five (5) calendar days as required. "Adverse event" is defined as "any adverse patient outcome related to sterile compounding process; or evidence of environmental contamination, including microbial contamination above the threshold set forth in USP 797 Standards." COMAR 10.34.19.03B(1). The Pharmacy also failed to report other deficiencies related to the sterile compounding process as observed in the FDA 483.
5. On April 4, 2018, the FDA issued a Warning Letter to the Pharmacy based on unresolved issues noted in the March 2017 FDA 483.
6. On August 17, 2018, the Pharmacy self-reported to the Board disciplinary action it received by the Missouri Board of Pharmacy based on the March 2017 FDA 483. The Missouri Board and the Pharmacy entered into a Settlement Agreement that imposed a one (1) year probation with terms and conditions to include monthly environmental testing. The Pharmacy has satisfactorily complied with the probationary terms and has been released from probation.
7. The Pharmacy was subsequently disciplined by the Florida Board of Pharmacy (August 2019) and Michigan Board of Pharmacy (December 2019) for the same or similar bases.

8. The FDA performed a re-inspection of the Pharmacy in or around May 2019 and took no further action.
9. The Pharmacy's Washington pharmacy permit is currently active without any disciplinary action of record.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, and in accordance with Md. Code Ann., Health Occ. §§ 12-403(c)(11), 12-403(g)(10) and COMAR 10.34.19.18, the Board resolves this matter as follows, in regard to Key Compounding Pharmacy, Permit Number P04568,

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it this 3rd day of February, 2020, hereby,

ORDERED that Key Compounding Pharmacy, Permit No. P04568, shall submit to the Board on a quarterly basis results of monthly environmental (surface and air) monitoring tests for a period of ONE (1) YEAR; and be it further,

ORDERED that Key Compounding Pharmacy shall comply with all laws and regulations governing the operation of a non-resident pharmacy in the State of Maryland, to include Maryland laws governing the reporting of adverse events relating to compounding and dispensing of sterile drug products; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-101, *et seq.*

2-3-2020

Date

Deena Speights Napata

Deena Speights Napata,
Executive Director for:

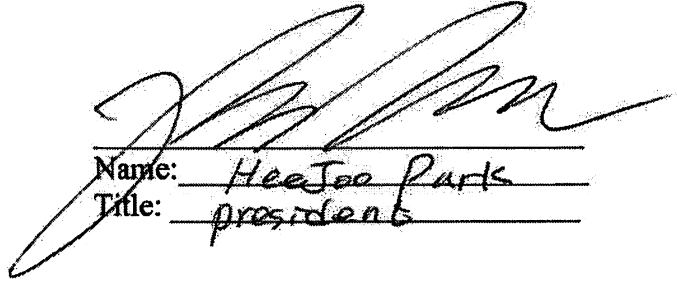
Kevin Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Key Compounding Pharmacy submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.
2. Key Compounding acknowledges the validity of this Consent Order as if it were made after a hearing in which it would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.
3. Key Compounding Pharmacy acknowledges that, by entering into this Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.
4. Key Compounding Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

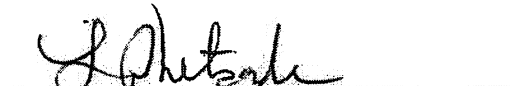
5. Key Compounding Pharmacy signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Key Compounding Pharmacy fully understands the language, meaning, and effect of this Consent Order.

01-31-2020
Date


Name: HeeJoo Park
Title: president

STATE OF Washington
COUNTY/CITY OF King:

I hereby certify that on this 31 day of Jan, 2020, before me, a Notary Public of the State of Washington and County/City aforesaid, personally appeared HeeJoo Park, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Key Compounding Pharmacy.


Notary Public
My commission expires: 7/29/20

