

IN THE MATTER OF

*

BEFORE THE

**PHARMEDIUM
SERVICES, LLC**

*

MARYLAND STATE

*

BOARD OF PHARMACY

PERMIT NO. D05791

Case No. 19-016

PERMIT NO. D05790

*

Case No. 19-069

PERMIT NO. D05789

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Case No. 19-070

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CONSENT ORDER

Background

On May 17, 2018, the Maryland Board of Pharmacy (the “Board”) received a report from the Alabama Board of Pharmacy regarding emergency action taken against PharMEDium Services, LLC, (“PharMEDium”) at the Memphis, TN facility, and Cleveland, MS, facilities based on FDA inspection observations and a recall of products distributed from the Memphis facility. Subsequently, PharMEDium submitted self-reports to the Board in August 2018 regarding disciplinary actions imposed by the Virginia and Nevada Boards of Pharmacy against the same facility locations, as well as its facility in Sugar Land, TX. The Board’s investigation revealed that the above-captioned facilities had been inspected by the FDA, issued FDA Form 483 observations detailing cGMP compliance issues, and some were issued Warning Letters regarding cGMP violations.

In lieu of instituting formal proceedings against PharMEDium, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and PharMEDium, have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. At all times relevant, PharMEDium held wholesale distributor permits issued by the Board for four (4) facility locations: Cleveland, Mississippi (Permit No. D05788); Memphis, Tennessee (Permit No. D05791); Sugar Land, Texas (Permit No. D05790); and Dayton, New Jersey (Permit No. D05789).
2. All of the above PharMEDium facilities are also registered with the FDA as outsourcing facilities.
3. As outsourcing facilities, PharMEDium compounds and distributes a variety of sterile products to its customers located in Maryland. PharMEDium compounds using only a sterile-to-sterile compounding process using only FDA-approved drug products.
4. The above facilities have been inspected by the FDA and received FDA Form 483's listing observations of repeated, unresolved issues relating to cGMP compliance. All but the Dayton, New Jersey facility have received FDA Warning Letters.

Cleveland, Mississippi

- FDA 483, issued 2/22/2013
- Warning Letter, dated 7/18/2014
- FDA 483, issued 7/16/2015 and containing 5 repeated observations
- FDA 483, issued 1/15/2018 and containing 9 repeated observations

Memphis, Tennessee

- FDA 483, issued 3/22/2013
- Warning Letter, dated 7/18/2014
- FDA 483, issued 7/10/2015 and containing 6 repeated observations
- FDA 483, issued 12/15/2017 and containing 1 repeated observation

Sugar Land, Texas

- FDA 483, issued 2/27/2013
- Warning Letter, dated 7/18/2014
- FDA 483, issued 9/24/2015 and containing 2 repeated observations
- FDA 483, issued 12/22/2017 and containing 2 repeated observations

Dayton, New Jersey

- FDA 483, issued 5/26/2016
 - FDA 483, issued 12/13/2017 and containing 5 repeated observations
5. As a result of the FDA inspections, PharMEDium issued voluntary recalls on December 27, 2017, and January 11, 2018, of products within expiry from the Memphis, TN facility. On September 1, 2017, it recalled certain Oxytocin products from the Sugar Land, TX facility.
 6. On or around November 30, 2017, PharMEDium ceased all production and commercial distribution at the Memphis, TN facility.
 7. On or around April 17, 2019, PharMEDium voluntarily and permanently ceased all compounding operations at the Cleveland, MS facility. All drug product distribution ceased by May 24, 2019 and, due to business reasons unrelated to any federal or state agency action, the facility will permanently close.
 8. PharMEDium has been subject to formal actions based on FDA's findings and observations as follows:
 - (a) On February 27, 2018, the California Board of Pharmacy issued an Order to Cease and Desist against the Sugar Land, TX, facility due to alleged cGMP violations.
 - (b) On May 15, 2018, Alabama Board of Pharmacy issued an Emergency Suspension of the permit held by the Cleveland, MS, and Memphis, TN facilities based on FDA's inspection observations and the recall of all products from the Memphis location.
 - (c) On July 17, 2018, the Virginia Board of Pharmacy issued a Suspension Order against the permit held by the Cleveland, MS, and Memphis, TN facilities, due to the Emergency Suspension issued by the Alabama Board.
 - (d) On August 20, 2018, the Virginia Board of Pharmacy issued a Suspension Order against the Sugar Land, TX, facility based on the California Order.
 - (e) On August 23, 2018, the Nevada Board of Pharmacy issued a Summary

Suspension of the permits held by the Cleveland, MS, and Memphis, TN facilities due to the suspensions by the Alabama and Virginia boards.

9. PharMEDium has responded to all of the FDA Form 483 observations with corrective actions at both the facility and corporate levels. It provided FDA with quarterly updates regarding progress of its remedial measures, with the last update provided on October 19, 2018.
10. PharMEDium submitted to the Board a detailed update of the status of completion for its corrective action plan, which demonstrates substantial progress, and targeted dates for full completion.
11. Representatives of PharMEDium met informally with members of the Maryland Board on April 10, 2019, to address concerns and discuss ongoing remedial activities.
12. On May 22, 2019, the United States District Court for the Northern District of Illinois entered a Consent Decree of Permanent Injunction between PharMEDium and the United States Department of Justice (on behalf of the U.S. Food and Drug Administration), which applies to PharMEDium's facilities in Dayton, New Jersey; Memphis, Tennessee; Sugar Land, Texas; and its Corporate Headquarters in Lake Forest, Illinois.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that PharMEDium Services, LLC, Permit Numbers D05791, D05790, and D05789, are subject to a formal order in accordance with Md. Code Ann., Health Occ. § 12-601(a) and COMAR 10.34.22.05A(3)(e) and (4).

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-601, it is this 1st day of August, 2019, hereby,

ORDERED that PharMEDium Services, LLC, shall submit quarterly reports to the Board of its product quality assurance program for the wholesale distributor facilities operating in Sugar Land, TX (Permit No. D05790) and Dayton, NJ (Permit No. D05789), to include any out-of-compliance findings as determined by a relevant state or federal agency, recalls or adverse drug experiences (in the manner described in 21 C.F.R. § 310.305) associated or potentially associated with any and all of Defendants' drugs; and be it further,

ORDERED that PharMEDium Services, LLC, shall provide the Board with notice within 3 business days of receipt of any FDA Form 483 observations issued to any of the facilities governed by this Order; and be it further,

ORDERED that PharMEDium Services, LLC, shall cease distribution of compounded sterile products from its Memphis facility (Permit No. D05791) unless and until it receives notice that FDA does not object to resumption of compounding for commercial distribution and provides immediate notice of such commencement to the Board; and be it further,

ORDERED that PharMEDium Services, LLC, shall comply with all laws and regulations governing the operation of a wholesale distributor of compounded sterile products in the State of Maryland, to include compliance with federal cGMP regulations and FDA guidance documents as applicable to outsourcing facilities and/or any

subsequent regulation that is designated as applying to outsourcing facilities; and be it further,

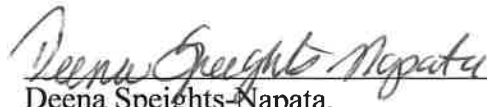
ORDERED that the Board reserves the right to take further action against PharMEDium Services, LLC, based on additional information that evidences a violation of the Maryland Pharmacy Act; and be it further,

ORDERED that PharMEDium Services, LLC, may petition the Board to be released from the terms of this Consent Order no earlier than TWO (2) YEARS from the date of this Order provided that PharMEDium provides documentation of satisfactory compliance with cGMP regulations and guidance for outsourcing facilities at the facilities governed by this Order; and be it further,

ORDERED that this formal order does not contain a “sanction” and is not considered disciplinary action pursuant to COMAR 10.34.11.02B(8); and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to the Maryland Public Information Act, Md. Code Ann., General Provisions Article § 4-301, *et seq.*

8-1-19
Date


Deena Speights-Napata,
Executive Director for:

Kevin Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, PharMEDium Services, LLC, submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. PharMEDium Services, LLC, 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. PharMEDium Services, LLC, 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. PharMEDium Services, LLC, acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

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

30-Jun-2019
Date


Name: K. Scott Aladeen
Title: President

STATE OF Illinois
COUNTY/CITY OF McHenry :

I hereby certify that on this 30th day of July, 2019, before me, a Notary Public of the State of Illinois and County/City aforesaid, personally appeared K. Scott Aladeen, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of PharMEDium Services, LLC.



Deborah S Taylor
Notary Public
My commission expires: March 6, 2023