IN THE MATTER OF	*	**BEFORE THE**
QUALGEN, LLC	*	**MARYLAND STATE**
Permit No. D05760	*	**BOARD OF PHARMACY**
	*	**Case No. 17-045**

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

SUPPLEMENTAL CONSENT ORDER

Background

In June 2016, the Maryland Board of Pharmacy (the "Board") received notification from the Food and Drug Administration ("FDA") that Qualgen, LLC, ("Qualgen") was issued an FDA Warning Letter citing certain violations relating to Qualgen's sterile compounding operations as an outsourcing facility registered with the FDA. The Oklahoma Board of Pharmacy ("Oklahoma Board") subsequently entered into an Agreed Findings of Fact, Conclusions of Law and Final Order against Qualgen based on, among other things, issues cited in the FDA warning letter. The Oklahoma Board also issued a fine against Qualgen in the amount of $100,000 and placed it on probation for five (5) years. The Board subsequently entered into a Pre-Charge Consent Order with Qualgen on June 11, 2018, which imposed a probation period to run commensurate with the Oklahoma Board's Order.

On June 15, 2021, and September 30, 2022, the FDA issued FDA 483 observations regarding further quality assurance issues at Qualgen, which resulted in a federal Consent Decree of Permanent Injunction, dated December 19, 2022 ("Consent Decree"). The Consent Decree prohibits Qualgen from manufacturing and/or distributing any products from Qualgen's facility until Qualgen demonstrates adherence to CGMP

requirements. Qualgen failed to notify the Board about the Consent Decree as required by the Board's regulations and the Pre-Charge Consent Order, dated June 11, 2018.

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

FINDINGS OF FACT

1. Qualgen, LLC, is licensed by the Oklahoma Board of Pharmacy as an outsourcing facility (I-B-4469) located in Edmond, Oklahoma. Qualgen is also registered with the FDA as an outsourcing facility.
2. Qualgen was issued a wholesale distributor's permit in Maryland on November 9, 2015 under Permit Number D05760. The Maryland permit is active and expires on May 31, 2025.
3. At all times relevant herein, Qualgen engaged in high-risk level sterile compounding of, among other things, hormone pellets for subcutaneous implantation.
4. In August and September 2015, the FDA conducted inspections of Qualgen's sterile compounding operations. As a result, the FDA issued an FDA Form 483 list of observations that cited various CGMP violations related in improper sterility testing, improper labeling, insufficient quality assurance procedures, environmental excursions, and facility deficiencies.
5. In October 2015, Qualgen responded to the FDA 483 and issued a voluntary recall of certain products.
6. On June 15, 2016, the Oklahoma Board of Pharmacy entered into an Agreed Findings of Fact, Conclusions of Law and Final Order against Qualgen based on the FDA's 483 observations. The Oklahoma Final Order placed Qualgen's license on probation

for five (5) years until June 15, 2021, with the ability to petition after one (1) year to lift the probation. The Oklahoma Final Order also fined Qualgen in the amount of $100,000.

7. In April and May 2017, the FDA conducted further inspections of Qualgen and observed approximately seventeen (17) CGMP violations, three of which were repeat issues observed in the 2015 inspection.
8. On June 11, 2018, the Board issued a Pre-Charge Consent Order against Qualgen generally mirroring the provisions of the Oklahoma Final Order and requiring that Qualgen submit to the Board "written notice to the Board of any complaint, deficiency or investigation of Qualgen, LLC, received, cited or otherwise filed with the Oklahoma Board of Pharmacy, or FDA."
9. The Oklahoma Board terminated Qualgen's probation on September 28, 2018. However, the Maryland Board denied Qualgen's request to terminate probation due to continuing issues identified by the FDA.
10. On June 15, 2021, and September 30, 2022, the FDA issued further FDA 483 observations regarding CGMP violations noted during inspections.
11. On December 19, 2022, the U.S. District Court, Western District of Oklahoma (Case CIV-22-1028-PRW) issued a Consent Decree ordering that Qualgen was prohibited from directly or indirectly manufacturing, holding, and/or distributing drugs manufactured at and/or from the facility, and requiring that it retain a CGMP expert and become compliant with all CGMP requirements. Once completed, Qualgen must retain an auditor to perform quarterly audits for one (1) year, and then semiannual audits for the next four (4) years. The audits and any corrective actions must be reported to the FDA.
12. Qualgen renewed its distributor's permit in Maryland in June 2023. Qualgen failed to notify the Board about the Consent Decree as required by the Board's regulations and the Pre-Charge Consent Order, dated June 11, 2018.

13. Qualgen also failed to report to the Board disciplinary actions it received from the boards of pharmacy in Missouri, New Hampshire, and Massachusetts.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Qualgen, LLC, Permit Number D05760, is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-601, § 12-6C-11, and COMAR 10.34.22I, 10.34.22.05A(4) and 10.34.22.07D.

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-601, it this 22nd day of October, 2024, hereby,

ORDERED that the PROBATION imposed by the Board's Pre-Charge Consent Order, dated June 11, 2018, on the distributor's permit held by Qualgen, LLC, Permit No. D05760, shall be continued until such time that Qualgen satisfies the requirements of the federal Consent Decree, dated December 19, 2022, issued by the U.S. District Court, Western District of Oklahoma; and be it further,

ORDERED that Qualgen, LLC, shall fully comply with the terms and conditions of such Consent Decree; and be it further,

ORDERED that Qualgen, LLC, shall immediately provide written notice to the Board of any complaint, deficiency or investigation of Qualgen, LLC, received, cited or otherwise filed with the Oklahoma Board of Pharmacy, or FDA; and be it further,

ORDERED that Qualgen, LLC, shall comply with all laws and regulations governing the operation of a wholesale distributor licensed in the State of Maryland, to

include Maryland laws governing the distribution of compounded sterile preparations; and be it further,

ORDERED that in the event Qualgen, LLC, violates any of the terms above, or any provision of the Maryland Pharmacy Act, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension, revocation, and fines, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that Qualgen, LLC, may petition the Board to terminate probation provided that Qualgen has fully satisfied all terms and conditions set forth herein; 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 § 4-301, *et seq.*

10/22/2024
Date

Deena Speights-Napata, M.A.
Executive Director for:

Kristopher Rusinko, Pharm.D.
Board President

CONSENT

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

2. Qualgen, LLC acknowledges the validity of this Supplemental 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. Qualgen, LLC acknowledges that, by entering into this Supplemental Consent Order, it is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Qualgen, LLC acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Supplemental Consent Order.

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

10/17/2024
Date

Name: Shaun P. Riney
Title: CEO

STATE OF OKLAHOMA,
COUNTY/CITY OF Edmond :

I hereby certify that on this 17th day of October 2024, before me, a Notary Public of the State of Oklahoma and County/City aforesaid, personally appeared Shaun P. Riney, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Qualgen, LLC.

VERA OLIVIA CALVERY
Notary Public, State of Oklahoma
Commission # 24008219
My Commission Expires 06-28-2028

Vera Olivia Calvery
Notary Public
My commission expires: 06-28-28