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

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

PRE-CHARGE 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 Order fined Qualgen in the amount of $100,000 and placed it on probation for five (5) years. Several other states have taken reciprocal disciplinary action based on the Oklahoma's Final Order.

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 Pre-Charge 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, 2019.
3. Qualgen engages in high-risk level sterile compounding of testosterone and estradiol pellets for subcutaneous implantation.
4. From August through 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 places 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. On March 25, 2016, the Alabama Board of Pharmacy issued a Final Order denying Qualgen's application for a non-resident pharmacy permit based on the FDA's 483 observations.
8. On February 7, 2017, the Oregon Board of Pharmacy issued a Consent Order against Qualgen based on the Oklahoma Final Order, dated June 15, 2016.
9. On August 16, 2017, the New Hampshire Board of Pharmacy entered into a Settlement Agreement with Qualgen based on the Oklahoma Final Order, dated

June 15, 2016.

10. On August 23, 2017, the Missouri Board of Pharmacy entered into a Settlement Agreement with Qualgen based on the Oklahoma Final Order, dated June 15, 2016.
11. From April through May 2017, the FDA conducted another inspection of Qualgen and observed approximately seventeen (17) cGMP violations, three of which were repeat issues observed in the 2015 inspection.
12. On September 26, 2017, the South Carolina Board of Pharmacy denied Qualgen's application for an outsourcing and manufacturer's permit based on the deficiencies observed in the April/May 2017 FDA 483.

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-09(b), and COMAR 10.34.22.05A(3)(e), (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 11th day of June, 2018, hereby,

ORDERED that Qualgen, LLC, Permit No. D05760, shall be placed on probation to run commensurate with the probationary period imposed by the Oklahoma Board of Pharmacy in its Agreed Findings of Fact, Conclusions of Law and Final Order, dated June 15, 2016; and be it further,

ORDERED that Qualgen, LLC, shall fully comply with the Oklahoma Board of Pharmacy Final Order, dated June 15, 2016; 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, 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 under the Oklahoma Board Final Order, dated June 15, 2016, and the Oklahoma Board has lifted the probation issued thereunder; 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 § 4-333.

6-11-18
Date

Deena Speights-Nabata
Executive Director for:

Kevin M. Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Qualgen, LLC, submits to the foregoing 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 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 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 Consent Order.

5. Qualgen, LLC signs this 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.

6/5/2018
Date

Name: SHAUN RINEY
Title: CEO

STATE OF OKLAHOMA
COUNTY/CITY OF OKLAHOMA:

I hereby certify that on this 5 day of JUNE, 2018, before me, a Notary Public of the State of OKLA and County/City aforesaid, personally appeared CONNIE AYERS, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Qualgen, LLC.

CONNIE B. AYERS
COMM. NO. 16010768
NOTARY PUBLIC
EXP. 11-09-2020
STATE OF OKLAHOMA

Notary Public
My commission expires: 11/9/2020