

IN THE MATTER OF	*	BEFORE THE
PACIFICO NATIONAL, INC.	*	MARYLAND STATE
dba AMEX PHARMACY	*	BOARD OF PHARMACY
PERMIT NOS. P03052/D06474	*	Case No. 20-061

* * * * *

CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) received notification that Pacifico National, Inc. dba AMEX Pharmacy (“AmEx Pharmacy”) was issued an FDA Form 483 on or about May 31, 2019, which included observations relating to violations of sterile compounding standards. On September 3, 2019, AMEX Pharmacy issued a voluntary recall of certain ophthalmic products as a result of FDA warnings to patients and healthcare professionals not to use sterile products compounded by AMEX Pharmacy. In addition, AMEX Pharmacy was subject to formal disciplinary actions by the South Carolina and Alabama Boards of Pharmacy based on the 2019 FDA 483, neither of which was reported to the Board as required.

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

FINDINGS OF FACT

1. On or about August 6, 2002, AMEX Pharmacy, located in Melbourne, Florida, was issued a non-resident pharmacy permit to operate in Maryland under Permit Number P03052. The Pharmacy’s permit is active and will expire on May 31,

2020.

2. On or about December 19, 2018, AMEX Pharmacy was issued a distributor's permit to operate in Maryland under Permit Number D06474. AMEX Pharmacy was also registered with the FDA as an outsourcing facility. This enabled AmEx Pharmacy to distribute non-patient specific compounded sterile products into Maryland.
3. AMEX Pharmacy dispenses patient and non-patient-specific sterile compounded products, to include ophthalmic products such as Bevacizumab injectables.
4. In April and May, 2019, the Food and Drug Administration ("FDA") conducted inspections of AMEX Pharmacy. Based on such inspections, on May 31, 2019, the FDA issued a Form 483 list of observations relating to certain deficiencies in AMEX Pharmacy's sterile compounding process.
5. On June 28 and August 27, 2019, the FDA issued warnings to patients and healthcare professionals not to use sterile products from AMEX Pharmacy based on conditions observed during the April-May 2019 inspections.
6. On September 3, 2019, AMEX Pharmacy issued a voluntary recall of all lots of Bevacizumab 1.25mg/0.05ml 31G Injectables and Bevacizumab 2.5mg/0.1ml Normject TB Injectables that were within expiry to the healthcare provider level.
7. AMEX Pharmacy shipped products into Maryland that were subject to the recall.
8. On May 13, 2019, the South Carolina Board of Pharmacy summarily suspended AMEX Pharmacy's permit.
9. On November 1, 2019, the Alabama Board of Pharmacy issued an Emergency Suspension of AMEX Pharmacy's permit based, in part, on the 2019 FDA 483.
10. AMEX Pharmacy failed to report to the Board both the South Carolina and Alabama Board of Pharmacy disciplinary actions as required.
11. On November 14, 2019, AMEX Pharmacy advised the Board that it ceased all sterile compounding operations in July 2019 and currently only compounds

patient-specific non-sterile products.

12. On September 23, 2019, AMEX Pharmacy unregistered with the FDA as a 503B outsourcing facility.
13. The Board previously issued formal disciplinary action against AMEX Pharmacy on September 6, 2017, based on violations sterile compounding standards observed in a prior FDA 483 and subsequent disciplinary action imposed by the Florida Board of Pharmacy.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that AmEx Pharmacy, Permit Numbers P03052 and D6474, is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-403(g)(1) and (10), 12-601, and COMAR 10.34.19.18B and 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. §§ 12-409 and 12-601, it this 4th day of March, 2020, hereby,

ORDERED that AMEX Pharmacy shall be REPRIMANDED; and be it further,

ORDERED that AMEX Pharmacy shall be prohibited from dispensing or distributing any compounded sterile drug products into the State of Maryland; and be it further,

ORDERED that AMEX Pharmacy may not resume dispensing or distributing compounded sterile drugs products into Maryland unless or until AMEX Pharmacy has provided to the Board evidence, in the Board's sole determination, demonstrating

compliance with USP 797 or cGMP sterile compounding standards, as applicable; and be it further,

ORDERED that in the event AMEX Pharmacy resumes the dispensing or distributing of compounded sterile drugs products into Maryland in accordance with the terms above, AMEX Pharmacy shall comply with all laws and regulations governing the operation of a non-resident pharmacy and distributor in the State of Maryland, to include Maryland laws governing the compounding of sterile drug products and reporting requirements; 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.*

3-4-2020
Date

Deena Speights-Napata
Deena Speights-Napata,
Executive Director for:

Kevin Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Pacifico National, Inc. dba AMEX Pharmacy (“AMEX Pharmacy”) submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.


2. AMEX Pharmacy 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. AMEX 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. AMEX Pharmacy acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

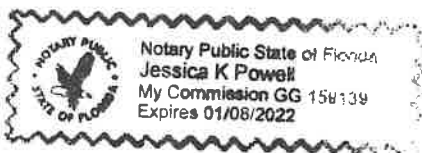
5. AMEX Pharmacy signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. AMEX Pharmacy fully understands the language, meaning, and effect of this Consent Order.

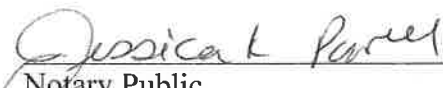
2/25/20
Date


Name: Mike Boehmer
Title: Director Research & Development
PSC

STATE OF Florida
COUNTY/CITY OF Broward/Melbor:

I hereby certify that on this 25th day of February, 2020, before me, a Notary Public of the State of Florida and County/City aforesaid, personally appeared Michael Boehmer, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of AMEX Pharmacy.




Notary Public
My commission expires: 1-8-2022