

IN THE MATTER OF PACIFICO NATIONAL, INC. dba AMEX PHARMACY Permit No. P03052	* * * *	BEFORE THE MARYLAND STATE BOARD OF PHARMACY Case No. PI-16-221
* * * * * * * * * * * *		

CONSENT ORDER

Background

In January 2016, the Maryland Board of Pharmacy (the “Board”) received notification from the Food and Drug Administration (“FDA”) that Pacifico National, Inc., dba Amex Pharmacy, (“Amex Pharmacy”) was issued an FDA 483 with inspectional observations relating to Amex Pharmacy’s sterile compounding operations. The Florida Department of Health (“FDH”) subsequently filed an Administrative Complaint with the Florida Board of Pharmacy against Amex Pharmacy based on the FDA 483. On February 21, 2017, the Florida Board of Pharmacy issued a Final Order against Amex Pharmacy in which the pharmacy was fined and placed on probation.

In lieu of instituting formal proceedings against 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. Pacifico National, Inc., dba Amex Pharmacy is a pharmacy located in Melbourne, Florida, holding non-resident pharmacy permit number P03052. The Maryland non-resident pharmacy permit expires on May 31, 2018.
2. Amex Pharmacy engages in the preparation of medium-risk level compounded

- sterile preparations of Avastin, a medication used to inhibit new growth of blood vessels and can be used off-label to treat macular degeneration.
3. In January 2016, the FDA and the Florida Department of Health conducted joint inspections of Amex Pharmacy's sterile compounding operations. As a result, the FDA issued an FDA Form 483 list of observations that cited various USP 797 violations related in improper aseptic techniques, insufficient quality assurance procedures, environmental excursions, and improper sterility testing.
 4. On February 29, 2016, the Florida Department of Health issued an Emergency Restriction Order against Amex Pharmacy based on the FDA's 483 observations. Amex Pharmacy ceased all sterile compounding in response to the Order. Subsequent to re-inspection by FDH and corrective actions taken by Amex Pharmacy, FDH rescinded its Emergency Restriction Order on April 22, 2016.
 5. On March 21, 2016, FDH filed an Administrative Complaint against Amex Pharmacy with the Florida Board of Pharmacy based primarily on the deficiencies observed in the FDA 483.
 6. On February 21, 2017, the Florida Board of Pharmacy issued a Final Order accepting a Settlement Agreement with Amex Pharmacy. The Order fined AmEx Pharmacy \$7,000, and placed the permit on probation for one year. Pursuant to the terms of the Final Order, Amex Pharmacy must also submit a written corrective action plan addressing the deficiencies cited in the Complaint, and is subject to semi-annual inspections.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Amex Pharmacy, Permit Number P03052, is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-403(g).

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it this 6th day of September, 2017, hereby,

ORDERED that Amex Pharmacy, Permit No. P03052, shall be placed on probation for ONE (1) YEAR, effective February 21, 2017; and be it further,

ORDERED that Amex Pharmacy shall fully comply with the Final Order Approving Settlement Agreement, issued by the Florida Board of Pharmacy, dated February 21, 2017; and be it further,

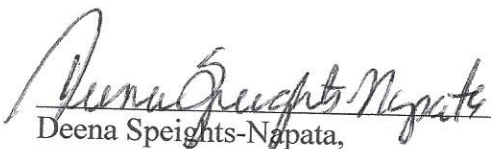
ORDERED that Amex Pharmacy shall immediately provide written notice to the Board of any complaint, deficiency or investigation of Amex Pharmacy received, cited or otherwise filed with the Florida Board of Pharmacy, Florida Department of Health, or FDA; and be it further,

ORDERED that Amex 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 compounding and dispensing of compounded sterile preparations; and be it further,

ORDERED that in the event that Amex Pharmacy 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 this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-333.

9/6/17
Date


Deena Speights-Napata,
Executive Director for:

Mitra Gavvani, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Pacific National, Inc., dba 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.

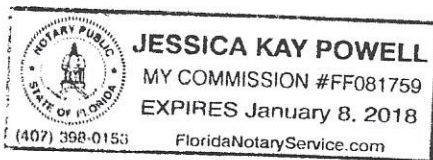
5. Amex Pharmacy signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Amex Pharmacy fully understands the language, meaning, and effect of this Consent Order.

8-31-17
Date

CBuhrman
Name: Christina Buhrman
Title: Pharmacist In Charge

STATE OF Florida
COUNTY/CITY OF Brevard / Melbourne

I hereby certify that on this 31st day of August, 2017, before me, a Notary Public of the State of Florida and County/City aforesaid, personally appeared Christina Buhrman, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Pacifico National, Inc., dba Amex Pharmacy.



Jessica Kay Powell
Notary Public
My commission expires: 1-8-2018