

**IN THE MATTER OF
AKINA PHARMACY
PERMIT NO. P06197**

*
*
*
*

**BEFORE THE
MARYLAND STATE
BOARD OF PHARMACY
CASE NO. PI-17-165**

* * * * *

CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) received notice that Akina Pharmacy (the “Pharmacy”) was issued an FDA 483 list of observations on August 10, 2016, regarding its sterile compounding operations. The Pharmacy was subsequently inspected and disciplined by the Virginia Board of Pharmacy on April 24, 2018. The Pharmacy failed to report the FDA 483 or the Virginia Board action to the Board as required. The Board’s investigation also determined that the Pharmacy was previously disciplined by the Virginia Board in June 2016, and by the South Carolina Board in May 2017, neither of which was disclosed to the Board on the Pharmacy’s renewal application in April 2018.

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

FINDINGS OF FACT

1. The Pharmacy is located in Chantilly, Virginia, and obtained a non-resident pharmacy permit to operate in Maryland under Permit Number P06197 on or about July 16, 2014. The Pharmacy’s permit is active and will expire on May 31, 2020.
2. The Pharmacy provides and dispenses compounded sterile products pursuant to

patient-specific prescriptions.

3. On or about August 10, 2016, the Food and Drug Administration (“FDA”) issued a Form 483 list of observations based on an inspection of the Pharmacy that indicated certain issues in the Pharmacy’s sterile compounding process. The Pharmacy responded to the FDA 483 on August 24, 2016. The FDA subsequently closed the case and referred the matter to the Virginia Board of Pharmacy.
4. On December 12, 2017, the Virginia Board conducted an inspection of the Pharmacy and noted certain deficiencies. As a result, the Virginia Board issued an Order against the Pharmacy on April 24, 2018, which included a fine in the amount of \$8,000.
5. The Pharmacy failed to report the Virginia Board’s April 2018 Order to the Board within five (5) calendar days, as required by the Board’s sterile compounding regulations.
6. The Board’s investigation also revealed that the Pharmacy was previously disciplined by the Virginia Board on June 30, 2016, and by the South Carolina Board of Pharmacy on May 15, 2017.
7. The Pharmacy failed to disclose both of the above disciplinary actions on its 2018 renewal application to the Board.
8. The Pharmacy has since engaged in remedial efforts to enhance its licensing monitoring processes to ensure compliance with requirements of permits held by the Pharmacy in other states.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Akina Pharmacy, Permit Number P06197, is subject to discipline in accordance with Md. Code Ann., Health Occ. §§ 12-403(g)(1) and (10), and COMAR 10.34.19.18.

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-409, it is this 26th day of June, 2019, hereby,

ORDERED that Akina Pharmacy, Permit No. P06197, shall pay a FINE in the amount of ONE THOUSAND DOLLARS (\$1,000.00) within sixty (60) days, in the form of a check made payable to the Maryland Board of Pharmacy, and sent to:

Wells Fargo Bank
c/o State of Maryland – Board of Pharmacy
Lockbox 2051
7175 Columbia Gateway Drive
Columbia, Maryland 21046
(Please include the Case No. PI-17-165 to ensure proper assignment.)

and be it further;

ORDERED that Akina 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 reporting of disciplinary actions; 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 § 4-101, *et seq.*

6-26-19
Date

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

Kevin Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Akina Pharmacy makes no admission of wrongdoing but submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.


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

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


6/25/2019
Date


Name: BASSEM GIRGIS
Title: PRESIDENT

STATE OF VIRGINIA
COUNTY/CITY OF FAIRFAX :

I hereby certify that on this 25th day of JUNE, 2019, before me, a Notary Public of the State of VIRGINIA and County/City aforesaid, personally appeared BASSEM GHIS, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of Akina Pharmacy.

PHILLIP C. HICKS
Notary Public
Commonwealth of Virginia
356049
My Commission Expires August 31, 2019



Notary Public
My commission expires: 08/31/2019