

IN THE MATTER OF

*

BEFORE THE

ANDA, INC.

*

MARYLAND STATE

PERMIT NO. D06004

*

BOARD OF PHARMACY

*

Case No. 19-027

* * * * *

PRE-CHARGE CONSENT ORDER

Background

The Maryland Board of Pharmacy (the “Board”) conducted an annual inspection of a Maryland licensed pharmacy (Pharmacy A) on December 8, 2017. During that inspection, it was determined that Pharmacy A’s Maryland Controlled Dangerous Substances registration had expired on May 31, 2017. Subsequent investigation revealed that Pharmacy A had purchased from ANDA, Inc., and ANDA, Inc. had distributed to Pharmacy A, approximately 500 various controlled dangerous substances between June 1, 2017, and December 11, 2017, during Pharmacy A’s lapse in CDS registration. At all times Pharmacy A held a valid Federal DEA registration and Maryland Pharmacy permit.

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

FINDINGS OF FACT

1. ANDA, Inc. is a wholesale drug distributor located and licensed in Weston, Florida.
2. ANDA, Inc. was issued a Maryland wholesale distributor permit, Permit No. D06004, on November 15, 2016. Such permit is active and will expire on May

31, 2021.

3. On or about December 8, 2017, the Board conducted an annual inspection on Pharmacy A, located in Baltimore, Maryland. During that inspection, it was determined that Pharmacy A's Maryland's Controlled Dangerous Substance (CDS) Registration had expired on May 31, 2017.
4. Subsequent investigation by the Board revealed that Pharmacy A continued to purchase controlled dangerous substances from ANDA, Inc., notwithstanding the expiration of Pharmacy A's CDS registration.
5. Specifically, Pharmacy A purchased approximately 500 controlled dangerous substance medications from ANDA, Inc., between June 1, 2017, and December 11, 2017, without an active CDS registration.¹
6. Wholesale distributors may not sell or transfer a prescription drug to a person who is not legally authorized to receive the prescription drug.
7. ANDA submits that its software system did not recognize Maryland's additional state permit requirement for controlled dangerous substances. ANDA has since updated its software system to enhance its ability to monitor the licensing and disciplinary status of its purchasing clients.
8. During the above mentioned time frame Pharmacy A held a valid DEA registration and a valid Maryland Pharmacy permit.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that ANDA, Inc. is subject to a civil monetary penalty in accordance with Md. Code Ann., Health Occ. § 12-6C-11 and COMAR 10.34.22.05.A(3)(k) and (v).

¹ However, Pharmacy A's DEA registration remained active during all relevant times in which it purchased controlled dangerous substances from ANDA.

ORDER

Based upon an affirmative vote of the Maryland Board of Pharmacy under the authority of Md. Code Ann., Health Occ. § 12-101, *et seq.*, it this 2nd day of December, 2019, hereby,

ORDERED that ANDA, Inc., Permit No. D06004, shall pay an Administrative Assessment in the amount of FIFTEEN THOUSAND DOLLARS (\$15,000.00), payable to the Maryland Board of Pharmacy within sixty (60) days of the date of this Order, and mailed to:

Wells Fargo Bank
Attn: State of Maryland – Board of Pharmacy
7175 Columbia Gateway Drive
Lockbox 2051
Columbia, Maryland 21046

NOTE: Please include the case number, 19-027, on your check or money order to insure proper assignment to this case; and be it further,

ORDERED that ANDA, Inc., shall comply with all laws and regulations governing the wholesale distribution of prescription drugs, including controlled dangerous substances, into the State of Maryland; and be it further,

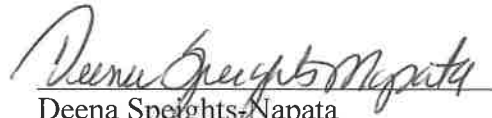
ORDERED that in the event that ANDA, Inc. violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any disciplinary sanction it deems appropriate, including suspension,

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 the Maryland Public Information Act, Md. Code Ann., General Provisions Article § 4-
101, *et seq.*

12-2-19

Date



Deena Speights-Napata
Executive Director for:

Kevin Morgan, Pharm.D.
Board President

CONSENT

1. By signing this Consent, ANDA, Inc., makes no admission to the facts but submits to the foregoing Pre-Charge Consent Order as a resolution of this matter in lieu of formal charges, and agrees to be bound by its terms and conditions.

2. ANDA, Inc., acknowledges the validity of this Pre-Charge 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. ANDA, Inc., acknowledges that, by entering into this Pre-Charge Consent Order, ANDA, Inc., is waiving its right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. ANDA, Inc., acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Pre-Charge Consent Order.

5. ANDA, Inc., signs this Pre-Charge Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. ANDA, Inc., fully understands the language, meaning, and effect of this Pre-Charge Consent Order.

11/21/19
Date

Jay Spellman
Name: Jay Spell
Title: Executive Director - Distribution & Regulatory Compliance

STATE OF FLORIDA,
COUNTY/CITY OF Bowling:

I hereby certify that on this 21st day of November, 2019, before me, a Notary Public of the State of Florida, County/City aforesaid, personally appeared Jay Spellman, and made an oath in due form that the foregoing Consent was his/her voluntary act and deed on behalf of ANDA, Inc.



Wendy Hope Lopresti
Notary Public
My commission expires: June 29, 2020