

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH \_\_\_\_\_)  
Check box below for type of ownership and complete all required forms.

☐ Publicly Traded Corporation – Pages 1,2,3,7

☐ Partnership – Pages 1,2,5,7

☒ Non Publicly Traded Corporation – Pages 1,2,4,7

☐ Sole Owner – Pages 1,2,6,7

### GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Axtells Rite Value Pharmacy Inc

Physical Address: 304 1/2 Charlie Street

Mailing Address: P O Box 9

City: Whitesboro State: TX Zip Code: 76273

Telephone: 903.564.3216 Fax: 903.564.7261

Toll Free Number: 855.203.3717 (Required per NAC 639.708)

E-mail: axtellaccounting@suddenlinkmail.com Website: axtellritevalue.com

Managing Pharmacist: James T Axtell Jr License Number: 19414

#### TYPE OF PHARMACY

AND

#### SERVICES PROVIDED

Yes/No

- ☒ ☐ Retail  
☐ ☒ Hospital (# beds N/A)  
☐ ☒ Internet  
☐ ☒ Nuclear  
☐ ☒ Ambulatory Surgery Center  
☒ ☐ Community  
☐ ☒ Other: N/A

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services  
☐ ☒ Parenteral \*\*  
☐ ☒ Parenteral (outpatient)  
☐ ☒ Outpatient/Discharge  
☒ ☐ Mail Service  
☐ ☒ Long Term Care  
☒ ☐ Sterile Compounding \*\*  
☒ ☐ Non Sterile Compounding  
☒ ☐ Mail Service Sterile Compounding \*\*  
☐ ☒ Other Services: \_\_\_\_\_

**\*\*If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

# APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☒ No ☐
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

**If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached.**

Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

Original Signature of Person Authorized to Submit Application, no copies or stamps

James T Axtell Jr

Print Name of Authorized Person

10-26-17  
Date

Page 2

Board Use Only

Date Processed: \_\_\_\_\_

Amount: \$500.00

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**State of Incorporation: TexasParent Company if any: N/AMailing Address: P O Box 9City: Whitesboro State: TX Zip: 76273Telephone: 903.564.3216 Fax: 903.564.7261

Contact Person: \_\_\_\_\_

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) James T Axtell Jr 304 1/2 Charlie Street, Whitesboro, TX 76273  
Name Addressb) Gina R Axtell 1640 Roland Rd, Whitesboro, TX 76273  
Name Addressc) N/A  
Name Addressd) N/A  
Name Address2) Provide the number of shares issued by the corporation. 10003) What was the price paid per share? \$1.004) What date did the corporation actually receive the cash assets? 12/30/1997

5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: James T Axtell Jr %: 50Name: Gina R Axtell %: 50**Hours of Operation for the pharmacy:**Monday thru ~~Friday~~ Thursday 8:00 am 7:00 pm Friday 6:00 pm Saturday 8:00 am 1:00 pm  
Sunday Closed am \_\_\_\_\_ pm 24 Hours \_\_\_\_\_A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

**Must be included with the application for a non publicly traded corporation**

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

*' See attached '*



STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

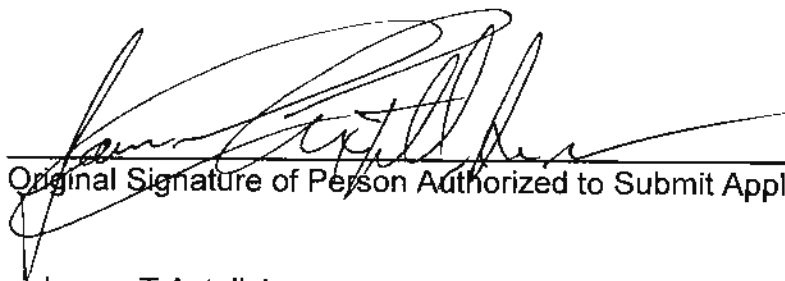
I, James T Axtell, Jr

Responsible Person of Axtells Rite Value Pharmacy Inc

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

James T Axtell Jr

Print Name of Authorized Person

10-26-17

Date

Pharmacy	License Number	Registration Date	Expiration Date		
<b>AXTELL RITE-VALUE PHARMACY</b>	19414	02/22/1999	02/28/2019		

Pharmacist-in-Charge/President	License Number	Registration Date	Expiration Date	F/T	P/T
JAMES THOMAS AXTELL, JR	36160	08/02/1996	02/28/2019	40	

Pharmacists	License Number	Registration Date	Expiration Date	F/T	P/T
BEDOLLA, JOE	21162	01/30/1975	05/31/2019		20
MCLENDON, MICHAEL	30773	11/25/2008	07/31/2020		20
MERRILL, DAVID	35328	05/01/1995	02/28/2019	40	
HAGAN, PATRICK	54889	07/03/2014	12/31/2017	40	

Technicians	Cert#	Registration Date	Expiration Date	F/T	P/T
AHL, ASHLYNNE	210638	03/31/2014	03/31/2018	40	
BAGWELL, LAURA	114614	05/04/2004	12/31/2017	40	
DURHAM, STEPHANIE	110597	07/21/2001	10/31/2019	40	
JOHNSON, MARK	124425	09/16/2004	03/31/2019	40	
MOFFITT, NICOLE WINKLER	101495	05/20/2004	04/30/2018		20
LEVERETT, REBECCA	102131		05/31/2019	40	
LOWRY, JIEZEL	241517	03/09/2015	03/31/2018		20
MCKINNEY, TERESA	222654		09/30/2018	40	
PATTERSON, TONI	112803	05/04/2004	05/31/2018	40	
RICHARDSON, DONNA MEEKS	137292	10/30/2006	03/31/2019	40	
VANDERGRIFF, BREE	173260	03/07/2011	05/30/2018		20



**RITE-VALUE  
PHARMACY**

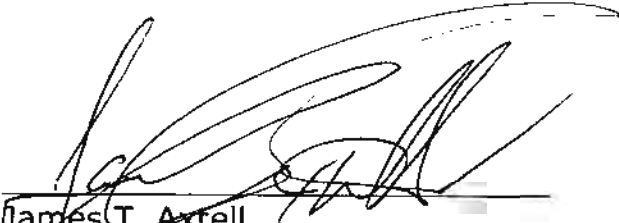
*and Compounding Center*

304 1/2 Charlie Drive Whitesboro, TX 76273  
903-564-3216 x210 Billing FAX: 903-564-7261  
Toll Free: 1-855-203-3717

Name: James T. Axtell Jr.  
DOB: 02/19/1969

Arrest: October 28, 2012  
Charge: Assault Family Violence  
Released on Bail: October 28, 2012  
Complaint Filed: January 14, 2013  
Dismissed: October 28, 2014

Attorney: Keith B. Brown  
124 S. Crockett St  
Sherman, TX 75090  
903.892.9131

  
James T. Axtell,  
President  
Axtells Rite Value Pharmacy Inc

10-26-17  
Date



## TEXAS STATE BOARD OF PHARMACY

**Re:** Axtell Rite-Value Pharmacy, Inc.  
**Address:** 304 1/2 Charlie Drive  
Whitesboro, Texas 76273  
**License No.:** 19414  
**Date Issued:** February 22, 1999  
**Licensure Status:** Active  
**Expiration Date:** February 28, 2019  
**Type of Pharmacy:** Community Sterile Compounding  
**Prior Disciplinary Orders:** Yes

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Axtell Rite-Value Pharmacy (Texas Pharmacy License #19414) has been subject to disciplinary action by the Texas State Board of Pharmacy (see attached).

Form Completed by:

Allison Vordenbaumen Benz, R.Ph., M.S.  
Director of Professional Services  
Texas State Board of Pharmacy

October 26, 2017  
Date



The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49<sup>th</sup> Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.





*Agreed Board Order #B-11-030*  
*Axtell Rite-Value Pharmacy Inc.*  
*Page 2*

An informal conference was held in the office of the Texas State Board of Pharmacy on September 5, 2012, with James Thomas Axtell, R.Ph., Pharmacist-in-Charge and Corporate President of Respondent; Gina Axtell, Corporate Vice President of Respondent; and Julie A. Nelson, Legal Counsel for Respondent, in attendance. The informal conference was heard by a Board panel comprised of: W. Benjamin Fry, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Caroline K. Hotchkiss, Staff Attorney, was also in attendance.

By appearing at the informal conference and by signing this Order, Respondent and Respondent's counsel neither admit nor deny the truth of the matters previously set out in this Order, and agree that the Board has jurisdiction in this matter and waive the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

#### **ORDER OF THE BOARD**

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

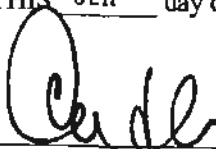
- (1) Respondent shall pay an administrative penalty of one thousand dollars (\$1,000) due ninety (90) days after the entry of this Order.
- (2) Respondent shall develop and implement policies and procedures to be used by pharmacy personnel to detect shortages and to prevent theft and loss of controlled substances. A written report of such policies and procedures shall be submitted to Board staff within ninety (90) days after the entry of this Order.
- (3) Respondent shall allow Board staff to directly contact Respondent on any matter regarding the enforcement of this Order.
- (4) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2011), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

Agreed Board Order #B-11-030  
 Axtell Rite-Value Pharmacy Inc.  
 Page 3

And it is so ORDERED.

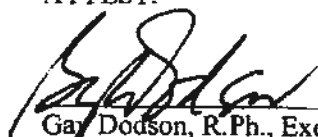
THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 6th day of November, 2012.



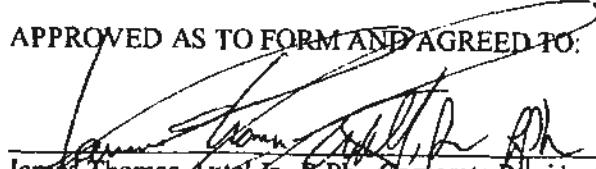
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

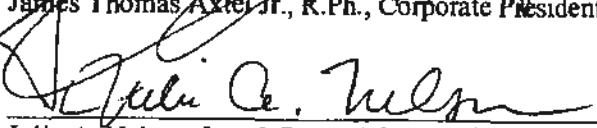


Gay Dodson, R.Ph., Executive Director/Secretary  
 Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

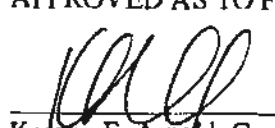


James Thomas Axtell Jr., R.Ph., Corporate President of Axtell Rite-Value Pharmacy Inc.



Julie A. Nelson, Legal Counsel for Axtell Rite-Value Pharmacy Inc.  
 Law Office of Julie Nelson, PLLC  
 1305 Crestwood Road  
 Austin, Texas 78722

APPROVED AS TO FORM:



Kersun E. Arnold, General Counsel  
 Texas State Board of Pharmacy

Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Artel Rite Value Pharmacy  
Address 30412 Charlie City Whitesboro State TX  
Pharmacist License # 21610  
NAME OF PERSON RESPONSIBLE Spencer Axtell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.133(d)(2)(D)(1)(VI)  
Explanation of violation Minimum product sterility testing when exceeding storage requirements of 25 days. Contacted AirScan, passed audit. Test cannot be used, may be needed.
2. Law/Rule 291.135(d)(14)(C)  
Explanation of violation Minimum record retention complete. 150 certification reports with rapid testing for 2 years. maintain all complete reports for 2 years.
3. Law/Rule 291.135(d)(14)(C)  
Explanation of violation Failure to maintain all balances with TSBP Register Balance for a total of 4 corrected.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/10/2018, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Agent, Texas State Board of Pharmacy  
Date 1/10/2018

Signed [Signature]

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Artel Rite Value Pharmacy

- ② Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

- STERILE PRODUCTS ARE TESTED INHOUSE. AQUEOUS 2 TUBE MEDIA AND RANDOM 3rd day testing will continue.
- CONTACTED AIRSCAN REQUESTED 2yr DOCUMENTATION OF COMPLETE REPORT FOR EACH 6 MONTH EVALUATION. WILL MAINTAIN REPORTS IN LAB FILING CABINET.
- HAVE REGISTERED ALL BALANCES WITH TSBP WEB SITE.

Additional comments:

Date 1/18/18

Signature of the person listed in the block titled "NAME OF PERSON RESPONSIBLE" must appear here.)

36/60  
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



## Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-500, Box 21

Austin, Texas 78701-3942

Phone: 512/305-8000

## WARNING NOTICE

Pharmacy License # 19414  
 Name of Facility Axtell Rite Value Pharmacy  
 Address 3411/2 Charles City Whitcomb Zip 78773  
 Pharmacist License # 36160  
 NAME OF PERSON RESPONSIBLE James Thomas Axtell Jr

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

## 1. Law/Rule

291.34 (a)

Explanation of violation Pharmacy maintains C-3 invoices & separates C-3 & C-2 invoices readily retrievable. 30 days of invoice retention & date handwritten. Separate C-3 invoices and maintain C-3 invoices readily retrievable.

## 2. Law/Rule

Pen to invoices, initial & date invoices

Explanation of violation

## 3. Law/Rule

291.34 (b)(1)(B)(i) & 291.34 (b)(1)(D)

Explanation of violation Pharmacy fails to control substance prescriptions issued by out-of-state nurse practitioners. Cease practice.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/10/2010, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Adrienne S. B...  
 Agent, Texas State Board of Pharmacy  
 Date 2/10/2010

Signed

## RESPONSE TO WARNING NOTICE

Pharmacy License #

Name of Facility

① Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

## Explanation of Correction:

1. FILES WILL BE KEPT IN LAB IN DESIGNATED FILE FOLDERS C-3-5 and C-2 SEPARATE FOR ALL BULK CHEMICALS

2. PHARMACIST ON DUTY WILL INITIAL ALL INVOICES PRIOR TO FILLING

3. PHARMACY WILL NO LONGER FILL AND SHIP TO OUT OF STATE NURSE MID-LEVEL PRACTITIONERS

Additional comments:

Date

01/18/10

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

License #

36160

②

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

### WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axell Rite Value Pharmacy  
Address 341 1/2 Charles City Wichita Falls State Texas  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE James Axell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 295.15 (c) & (g)  
Explanation of violation Failure to maintain documentation of RPH 20hr immunization course and CPR training. Failure to notify PCP of immunization maintenance 12 hr RPH
2. Law/Rule immunization training and document  
Explanation of violation CPR training. Notify patients PCP of immunization

3. Law/Rule 291.51 (d)(5)(C)(ii) & (iii)  
Explanation of violation Failure to maintain data beyond BUDs of non-sterile products. maintain valid scientific data when extending BUD beyond above referenced rules

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/20/2018 disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By Adrianna Salas  
Agent, Texas State Board of Pharmacy  
Date 1/10/2018

Signed [Signature]

30 Day

### RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axell Rite Value Pharmacy

☒ Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected, DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

#### Explanation of Correction:

1. \_\_\_\_\_
2. PROOF OF IMMUNIZATION FORM SENT WITH ALL REQUIRED INFO FAXED TO PCP.
3. NON STERILE PRODUCTS WILL BE TESTED BY OUTSIDE SOURCE OR LITERATURE BACK UP BY COMPOUNDING TODAY OR OTHER SOURCES

#### Additional comments:

Date \_\_\_\_\_

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.) \_\_\_\_\_

License # \_\_\_\_\_

☒ Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Art's Rite Value Pharmacy  
Address 2412 Charles Columbus St. 78705  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE James A. Taylor

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law Rule 291.33(c)(1)(B)(C)  
Explanation of violation Link Service: patient is denied new prescription pickup. Non-RPh personnel staff ask questions of patients that limit interaction with RPh.
2. Law Rule 291.33(c)(1)(B)(iv)  
Explanation of violation Pharmacist must maintain accurate records of RPh providing computer with new prescriptions. Accurate document must also be provided to RPh providing discharge.
3. Law Rule \_\_\_\_\_  
Explanation of violation \_\_\_\_\_

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 1/11/12, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By James A. Taylor  
Agent, Texas State Board of Pharmacy  
Date 1/9/12

Signed \_\_\_\_\_

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Art's Rite Value Pharmacy

- ② Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

1. All NEW RX'S will be counseled By PHARMACIST. FINGER PRINT
2. FINGER PRINT BIO IDENTIFIER was purchased 11/18, Received 1/11. Process Initiated 1/12
3. \_\_\_\_\_

Additional comments: \_\_\_\_\_

Date 1/11/12

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

License # 36160

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

### WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Rite-Value Pharmacy  
Address 412 Charlie Dr. Whitesboro, TX 72723  
Pharmacist License # 36160  
NAME OF PERSON RESPONSIBLE Jane Vandergriff

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law Rule 291.133(C)(4)(L)(V)  
Explanation of violation Failure to conduct initial  
guided fingertip testing. Conduct testing  
for all CSP staff & document.
2. Law Rule 291.133(C)(4)  
Explanation of violation Failure to maintain in-house OJT  
training for Jane Vandergriff. Re-evaluation  
of guided fingertip testing and medication for  
James Anderson. Conduct and document  
re-evaluation. Maintain files under training  
Explanation of violation 4 month. 9 month training  
documents signed by licensee and  
trainer.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 2/9/2018, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

Signed [Signature]  
Agent, Texas State Board of Pharmacy  
Date 1/9/2018

Signed

[Signature]

11/00

30 day

### RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Rite-Value Pharmacy

(P) Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

#### Explanation of Correction:

1. Bi-Annual Fingertip test will continue along with a re-initial test for All Acute Care Qualified Technicians
2. Jane Vandergriff OJT was found in another file and moved to OJT file. Jazel Lowrey will conduct Fingertip Test. She has moved from Fulltime to Part Time.
3. All PART TIME Employees and of New Employees will be put on the same Bi-Annual Shadow, Fingertip, Media Test Dates and Signatures.

Additional comments:

Date 1/18/18

Signature (The person listed in the blank titled NAME OF PERSON RESPONSIBLE must sign here.)

36160  
License #

(P) Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-800, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axel Rite Value Pharmacy  
Is hereby given that you are not complying with the following laws and or rules  
governing the practice of pharmacy:

- Rule 291.32(4)(3)  
Violation Pharmacist maintain profile  
to pharmacist rates 1st intention  
per rate at all times
- Rule 291.33(6)(3)  
Violation Pharmacist maintain profile  
to pharmacist rates 1st intention  
per rate at all times
- Rule 291.32(4)(3)  
Violation Pharmacist maintain profile  
to pharmacist rates 1st intention  
per rate at all times
- Rule 291.32(4)(3)  
Violation Pharmacist maintain profile  
to pharmacist rates 1st intention  
per rate at all times

also hereby given that unless the conditions noted above are corrected and a written  
filing the corrections is submitted to the Executive Director/Secretary of the Texas  
Board of Pharmacy on or before 1/19/18, disciplinary action may be  
taken against your license.

I hereby acknowledge that the laws and or rules  
cited above have been explained to me and that  
I have received a copy of this notice.

[Signature]  
Texas State Board of Pharmacy  
1/19/18

Signed [Signature]

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axel Rite Value Pharmacy

① Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions  
were corrected, DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN  
COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON  
THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

- Pharmacist Shifts 8AM 1st  
10AM 2nd, 11AM 3rd  
Will maintain Ratio
- END plan is to close Dinefield  
Pharmacy in 30 days until tech  
will no fill until 2nd shift  
or pharmacist is present
- Log Sig Sheet for Full Time  
PK

Additional comments:

Date 1/11/18

Signed (The person listed in the blank titled  
"NAME OF PERSON RESPONSIBLE" must  
sign here.)

36160  
License #

① Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy  
for your files.



Texas State Board of Pharmacy  
333 Guadalupe Street, Suite 3-500, Box 21  
Austin, Texas 78701-3942  
Phone: 512/305-8000

# WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Life Value Pharmacy  
Address 2412 E. 12th St. City Wichita Falls, TX Zip 76793  
Pharmacist License # 24140  
NAME OF PERSON RESPONSIBLE James Thomas Axtell

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule 291.122 (1)(6)  
Explanation of violation Humidity is not compliant with ISPP rules. In both the ante room & clean room the humidity is not at 60% (range 55-65%)
2. Law/Rule 291.122 (1)(7)  
Explanation of violation Pressure is not compliant with ISPP rules. In both the ante room & clean room the pressure is not at 0.02
3. Law/Rule 291.122 (1)(8)  
Explanation of violation Cracks & crevices are not sealed. All cracks & crevices are sealed with silicone caulk. Blemishes have been fixed on walls. All panels & light fixtures have been sealed. We installed stainless shelves for storage off floor.

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before 4/10/18 disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By James Thomas Axtell  
Agent, Texas State Board of Pharmacy  
Date 4/10/18

Signed James Thomas Axtell

## RESPONSE TO WARNING NOTICE

Pharmacy License # 19414  
Name of Facility Axtell Life Value Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.

### Explanation of Correction:

1. Clean room Designs has installed thermometers & humidity meters in NON-haz ante room & installed humidity meters in both ante rooms. We are able to monitor both rooms to maintain  $\pm 68^{\circ}\text{F}$  &  $\pm 60\%$  humidity.
2. We have made adjustments to maintain NON-haz clean room at a minimum pressure of 0.02
3. We have repainted w/ epoxy paint & tested w/ alcohol wipe. The cracks & crevices & seams have all been silicone caulked. Blemishes have been fixed on walls. All panels & light fixtures have been sealed. We installed stainless shelves for storage off floor.

Additional comments:

2-13-18

Date

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

19414 36160  
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.



Phcy Lic # <u>19414</u>
Expiration Date <u>2/29/19</u>

**NOTICE OF INSPECTION**  
 Texas State Board of Pharmacy  
 333 Guadalupe Street, Suite 3-500  
 Austin, Texas 78701-3942  
 (512) 305-8000

<input type="checkbox"/> Compliance
<input checked="" type="checkbox"/> Investigation

Name of Individual <u>Patrick Hagen</u>	Title <u>RPh</u>	R.Ph. Lic. # <u>54889</u>	Expires <u>12/18</u>
Name of Facility <u>Axkh Rite-Value Pharmacy, LLC</u>	Class of Pharmacy License <u>AS</u>		
Address <u>304 1/2 Charles Drive</u>			
City/State <u>Whiteword TX</u>	Zip <u>76273</u>	Phone # <u>(817) 544 3214</u>	
DEA Registration # <u>BA6242762</u>	Expiration Date <u>6/20</u>		
Date <u>Jan 9, 2018</u>	Time of Entry <u>945am</u>		

**PURPOSE OF INSPECTION**

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Routine                         | <input type="checkbox"/> Pre-Inspection                    | <input type="checkbox"/> Rank Change                                |
| <input type="checkbox"/> New Pharmacy                    | <input type="checkbox"/> Change of Ownership               | <input type="checkbox"/> Reverse Rank Change                        |
| <input type="checkbox"/> Complaint                       | <input checked="" type="checkbox"/> Follow-up to Complaint | <input checked="" type="checkbox"/> Licensee Request                |
| <input type="checkbox"/> Follow-up to Warning Notice     | <input type="checkbox"/> Follow-up to Theft/Loss Report    | <input checked="" type="checkbox"/> Sterile Compounding (High Risk) |
| <input type="checkbox"/> Follow-up to Disciplinary Order | <input type="checkbox"/> Other _____                       |   |

**ACKNOWLEDGEMENT**

This is to acknowledge that Texas State Board of Pharmacy Agent Adrianne M. Bauer has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

- I am the RPh for the above-described facility.
- I have read this Notice of Inspection and understand its contents and purpose.
- I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority.
- I have had the purpose of the entry into the above-described facility by the Board's agent stated to me, and
- I have consented to an inspection of the above-described facility voluntarily and without any manner of threats

Witnesses:

Adrianne M. Bauer  
 Signature

\_\_\_\_\_  
 Signature

Adrianne M. Bauer  
 Signature



# TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: A (A-S B C C-S (BEDS) D Other

Name of Pharmacy  
Pharmacist in Charge  
Personnel

Arkell Life Value Pharmacy Inc  
James Thomas Carter  
Scattered

TSBP License #

19414

Lic 34110 Exp 2/19

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

Lic \_\_\_\_\_ Exp \_\_\_\_\_

KEY: Circled items need improvement, ✓ items in Column One Refer to Legal Division (R/L) for review and possible discipline.  
✓ items in Column Two receive a Warning Notice (W/N)  
For an explanation of specific violations noted, refer to remarks section of inspection report

R/L	W/N		R/L	W/N		R/L	W/N	
		1 Licenses not posted			1 Date of last inventory			10 Rxs not separated
		2 Insufficient Equipment	15		No PIC inventory	35		Invoices not separated
		3 Orderly/Clean	69		No annual inventory	67		No written information
		4 Balance Failed	68		No change of ownership inventory	21		Computer records incomplete
		5 Equipment Inspection	31		Closed Phcy/Change of owner improper	22		Computer system noncompliance
		6 Inadequate Library	17		Incomplete inventory	82		PMR Incomplete
		7 Improper security	18	✓	Records not available	83		PMR Absent
		8 Environment	46		Improper distribution	84		No drug regimen review
		9 Delinquent licenses/certifications	54		Improper prepackaging procedures	16		No perpetual inventory
		36 No notification of substitution	24		Theft/Loss not reported	27		Improper inpatient records
90		No complaint notification	30		Invoices not dated/initialed	51		Improper ER dispensing
38		Area for non sterile compounding	86		Absence of RPh pick up records	75	✓	Improper absence of RPh procedures
43		Records for non sterile compounding	19		Rx lacks proper information	70		No P&P manual
47		Out of date/mislabeled drug stock	25		No documentation of refill authorization	71		Incomplete P&P manual
48		Improper drug storage	32		Rx label is incorrect	72		Improper procedures for IV preparation
53		Illegal possession of C/S	40		Non emergency C-II Rx	81		Area for preparation of sterile products
57		Corresponding Responsibility	26		C II Rx noncompliance	85		Patient Care Guidelines incomplete
59		Improper drug destruction	37		Illegal dispensing	87		Quality Control/Assurance
61	✓	Improper supervision of supportive personnel	45		Improper dispensing/labeling	88		Cytotoxic/Biohazardous Procedures
62		Aiding and abetting	44		Refill CIII-V over 5x/6mo	89		Refrigerator Temperature Log
65		Improper registration procedures	55		Refill prn past one year	28		No provision log
66		Grey Market diversion/Samples	78		Counseling area	29		Incomplete provision log
76	✓	No PIC (fulltime)	80		No counseling by RPh	52		Improper provision/dispensing in Class D
34		Notification Violation	56		Improper transfer of Rx	63		Prohibited drugs in Class D pharmacy
79		Names tags	50		Out of state verbal Rx for C/S	64		Violation of limited formulary
60		Improper documentation of training	49		Substitution noncompliance	91		RPh visits/contact documentation
92		Improper automated dispensing procedures	33		Rx records not in numerical order	73		Formulary not complete



# Texas State Board of Pharmacy

Inspection Report for Pharmacies Compounding Sterile Preparations

Circle One: Class A-5 Class B Class C-5

Name of Pharmacy

TSPB License #

Deficiency key: Cited items need improvement (N/I). Refer to Legal Division (R/L) for review and possible discipline, and Warning Factors (W/N) which require a written response with an explanation of correction(s). For an explanation of specific violations noted, refer to remarks section of inspection report. Note: "M" = Multiple Codes

R/L Code W/N

Environment	
M	Is cleanroom clean/free of objects that shed particles? (109) Contains only appropriate supplies? (110) Used only for sterile prep? (120)
M	Does ante-area provide at least ISO Class 8 under dynamic conditions? (101) Contain a hands-free sink with hot/cold running water? (115)
M	Does buffer area provide at least ISO Class 7 under dynamic conditions? (102) Area free from sources of water (e.g., sink/floor drains)? (106)
108	Is there hands-free access to the buffer area?
113	Are floors, walls, ceilings & fixtures smooth/impermeable and free from cracks & crevices? Does floor covering enable regular disinfection? (117)
118	Are supplies stored above the floor to permit adequate floor cleaning?
127	Does the clean room have a pressure gauge or velocity meter to monitor pressure differential between buffer area/room and ante-area/room and between the ante-area/room and the general environment? Pressure between ISO 7 & general environment shall not be less than 0.02" water column
M	Are temperature and humidity monitored (documented) and within required range? (116) Thermometer available for cleanroom and refrigerator? (167)
Primary Engineering Control (PEC) Device - i.e., Laminar Air Flow Hood, BSC, CAI, or CACI	
126	Is the Laminar air flow hood located in a buffer area that has a minimum differential positive pressure of 0.02-0.05" water?
121	Is the PEC able to maintain at least ISO Class 5 conditions, while compounding sterile preparations?
M	Are hazardous drugs prepared in a Class II or III vertical flow BSC or CACI located in an ISO 7 area physically separated from other areas? (246)
M	Does the BSC or CACI have not less than 0.01" negative pressure adjacent to the positive pressure ISO 7 environment? (247)
M	Does the CAI provide unidirectional flow? (105) If the CAI or CACI is used for high risk compounded sterile preparations, then is the CAI/CACI placed in an ISO 8 environment? (104)
122	If the CAI is not required to be placed in an ISO 7 environment, does the pharmacy maintain documentation from the manufacturer?
M	PEC certified by independent contractor every 6 months & when relocated? (124) Are prefilters inspected periodically & replaced as needed? (125)
128	Are differential pressures monitored and documented at least every work shift (minimum daily) or by a continuous recording device?
Equipment and Supplies	
M	Does the pharmacy have disposable needles, syringes, and other required or applicable supplies? (174) Does the pharmacy have lint-free towels or wipes? (177) Does the pharmacy have masks, caps, gowns with tight cuffs, shoe covers, and beard covers? (180)
M	Does pharmacy have handwashing agents w/ bactericidal action? (176) Disinfectant cleaning solutions and dedicated cleaning supplies? (175)
M	Does the pharmacy have hazardous spill kits, if applicable (179)? Appropriate disposal containers for needles and syringes? (171)
170	Does the pharmacy have sterile IPA, sterile gloves, and waterless alcohol-based surgical hand scrub?
178	Does the pharmacy have appropriate filters and filtration equipment?
181	If an automated compounding device is used, does the pharmacy calibrate & verify the device for accuracy on a daily basis-Is it documented?
172	Does the pharmacy have packaging or delivery containers to maintain proper storage conditions for sterile preparations?
High-Risk Sterile Preparations (CSPs)	
103	If high-risk CSPs are compounded, does buffer area provide physical separation from other compounding areas?
M	Is sterility testing performed under the following conditions: CSPs prepared in groups > 25? (231) MDV prepared for multiple pts or when exposed > 12 hrs at 2-8°C before sterilized? (232) Exposed > 6 hrs at warmer than 8°C before sterilized? (233)
237	Are all non-sterile measuring, mixing, and purifying devices rinsed thoroughly with sterile, pyrogen free water, and then thoroughly drained or dried immediately before use for high-risk compounding?
238	Are all high-risk sterile solutions subjected to terminal sterilization prefiltered using no larger than a 1.2 micron filter to remove particulate matter? Sterilization by filtration shall be performed with a sterile 0.2 micrometer or 0.22 micrometer pore size filter within an ISO Class 5 environment or better
165	Are filter integrity tests being performed and documented (e.g., bubble point)?
239	Are pre-sterilization procedures (weighing & mixing) completed in an ISO Class 8 environment or better?
Library	
M	Does the pharmacy have: Reference on injectable drugs (154), Specialty Reference (155), Applicable USP Chapters (156)?

R/L Code W/N



Hazardous Sterile Preparations			
M		Do personnel wear protective apparel (242); use safety/containment techniques (243); dispose of waste appropriately (244); affix proper label (245)?	
248		If using a BSC or CACI, does pharmacy have a pressure indicator that can be readily monitored for correct room pressurization?	
249		Does pharmacy meet the requirements for low volume preparation of hazardous drugs by using a device that provides two-tiers of containment?	
250		Are hazardous drugs stored separately from other inventory in a manner to prevent contamination and personnel exposure?	
Personnel Cleansing, Garbing and Hand Hygiene			
202		Does hand sanitizing and gowning occur in the ante area (outside the buffer area)? Do compounding personnel don clean non shedding gowns with sleeves that fit snugly around wrist and enclosed at the neck. Is the order of garbing appropriate? (180)	
M		Do personnel remove cosmetics (194); hand, wrist, and body jewelry or piercings (195); artificial nails? Are natural nails kept neat and trim? (196) Do personnel remove debris underneath fingernails using nail cleaner under warm water? (200)	
192		Are personnel with apparent illness or open lesions compounding sterile preparations?	
241		When personnel temporarily exit the ISO 7 environment, are re-donning procedures properly followed?	
M		Do personnel engage in proper hand hygiene? (201) Do personnel dry hands and forearms using lint free disposable towels or hand dryer? (201)	
204		Is antiseptic hand cleansing performed using waterless alcohol-based surgical scrub once inside buffer area & prior to donning sterile gloves?	
206		Is sterile IPA applied to gloves throughout the day & when non-sterile surfaces are touched?	
Cleaning and Disinfection Procedures			
182		Does pharmacy have written procedures regarding cleaning & disinfecting (e.g., beginning of shift, every 30 minutes, before each batch, & spills)?	
230		Is cleaning performed by trained personnel using approved agents (described in written SOPs)?	
228		Are supplies and equipment that are removed from shipping cartons wiped with a disinfecting agent - such as sterile 70% IPA?	
M		Are all areas properly cleaned? Daily (floors, DCA)? (226) Weekly, Monthly (walls, ceilings, shelving)? (227) Does pharmacy maintain documentation of cleaning procedures (i.e., date/time of cleaning, type of cleaning, and name(s) of person(s) carrying out the cleaning)? (229)	
Environmental Sampling			
271		Is surface sampling conducted in all ISO classified areas on a periodic basis? Are these results evaluated and addressed? (270) i.e. Action Levels followed?	
M		Is viable air sampling performed? (272) And documented by properly trained individuals for all risk levels every 6 months? (273)	
Records of Compounded Sterile Preparations			
252		Does the pharmacy maintain records relating to CSPs for a minimum of 2 years?	
M		Do records include: date (253); formula (254); who prepared (255); who checked (256); quantity (257); container used and number of units prepared (258); criteria for BUD (259); and documentation of performance of quality control procedures? (260) Other?	
M		Are batch compounding records complete? (261) Are master worksheets developed and approved by RPh (262)?	
General Operational Requirements			
166		Is RPh available at all times (24/7)?	
M		Are written SOPs followed to ensure accountability, accuracy, quality, safety, and uniformity? (187) Does pharmacy have all required written procedures (e.g., pharmaceutical care services, viable air sampling plan, and recalls)? Does pharmacy follow recall procedures? (188)	
158		If pharmacy compounds commercially available products, does pharmacy meet requirements for such compounding?	
275		Does pharmacy dispense prescriptions to patients in other states without proper licensure in those states?	
Office Use Compounding/Distribution			
163		Does pharmacy have written agreement with prescriber? Does written agreement meet all requirements?	
162		If pharmacy is distributing compounded sterile preparations to another pharmacy, does pharmacy meet requirements for such distribution?	
Quality Control and Verification of Compounding Accuracy			
207		Does a RPh review all compounding records for accuracy and perform final check? Are periodic in-process checks defined in written procedures? (185)	
191		Are all drug components manufactured in an FDA-registered facility? Are Certificates of Analysis available, if applicable?	
Label			
M		Is CSP properly labeled to include: generic name (209); compounded by pharmacy (210); BUD (211)? If prepared in batch, do labels contain: unique lot# (213); quantity (214); cautionary statements (215); and device-specific instructions, if applicable (216)?	
220		Are CSPs assigned a beyond use date that is based upon the specified labeling for the drug, appropriate literature sources, and/or direct testing?	
Training and Competency Testing			
129		Has each pharmacist completed the required education and training prior to engaging in sterile compounding?	
130		Has each pharmacy technician completed the required education and training prior to engaging in sterile compounding?	
142	✓	Does the pharmacy maintain documentation to demonstrate that all compounding personnel have successfully passed initial competency evaluation and testing (e.g., media fill testing, gloved fingertip/thumb testing)? Does pharmacy have an on-the-job training program?	
144	✓	Does the pharmacy maintain documentation of on-going training and testing for all compounding personnel?	



Ordered to

Remarks

Cell 4434-NI. Ensure delivered prescriptions include the following statements: "Complaints Concerning: 1891.3 Pa (D)(A)(ii) and "Written Information..." 291.33(c)(1)(F)(iii)  
 Cell 1942. Ensure prescription drug label includes brand name, generic name, strength, and name of prescriber.  
 Cell 45-NI. Ensure prescription label bears a statement indicating it is a compounded product. Ensure label bears "For Office Use Only - Not for Resale."  
 Cell 195-NI. Ensure SOPs address RPh in process checks of office use products

Action Taken

See warning notices

- (1) ☒ Inspection  
 (2) ☐ Pre-Inspection  
 (3) ☐ Partial Inspection  
 (4) ☐ Visit  
 (5) ☐ Other \_\_\_\_\_

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Adrian Medina  
 Agent of the Texas State Board of Pharmacy

1/9/2020  
 Date

4:30pm  
 Time of Exit

Authorized Individual for the Pharmacy

James Thomas Axell, Jr. RPh  
 Printed Name and Title of Authorized Individual



Phcy. Lic. # 19414  
 Expiration Date: 2/20/19

**NOTICE OF INSPECTION**  
 Texas State Board of Pharmacy  
 333 Guadalupe Street, Suite 3-500  
 Austin, Texas 78701-3942  
 (512) 305-8000

☐ Compliance  
☒ Investigation

Name of Individual <u>Patrick Hagan</u>	Title <u>RPh</u>	R.Ph. Lic. # <u>54889</u>	Expires <u>12/18</u>
Name of Facility <u>Axlell Rite-Value Pharmacy, Inc</u>		Class of Pharmacy License <u>A S</u>	
Address <u>304 1/2 Charlie Dr.</u>			
City/State <u>Wintersboro, TX</u>	Zip <u>76773</u>	Phone # <u>(817) 564-3216</u>	
DEA Registration # <u>BA 6242767</u>		Expiration Date <u>6/20</u>	
Date <u>Jan 10, 2018</u>		Time of Entry <u>9:15am</u>	

**PURPOSE OF INSPECTION**

- ☐ Routine  
☐ New Pharmacy  
☐ Complaint  
☐ Follow-up to Warning Notice  
☐ Follow-up to Disciplinary Order  
☐ Pre-Inspection  
☐ Change of Ownership  
☐ Follow-up to Complaint  
☐ Follow-up to Theft/Loss Report  
☒ Other Continue Inspection from 1/9/18  
☐ Rank Change  
☐ Reverse Rank Change  
☐ Licensee Request  
☐ Sterile Compounding (High Risk)

**ACKNOWLEDGEMENT**

This is to acknowledge that Texas State Board of Pharmacy Agent Adrian N. Bauer has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

- I am the RPh for the above-described facility;
- I have read this Notice of Inspection and understand its contents and purpose;
- I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
- I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
- I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

Signature [Signature]

Witnesses:

Signature [Signature]

Signature \_\_\_\_\_



**TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT**

CLASS:    A   A-S   B   C   C-S (BEDS   )   D   Other

**Name of Pharmacy**

**Pharmacist in Charge**

**Perceived**

TEEP License #

14

Ex

11

Ex

Uc

10

11

22

LE

10

**KEY:** Circled items need improvement. - Items in Column One Refer to Legal Division (R/L) for review and possible discipline

• **Items in Column Two receive a Warning Notice (W/N).**

For an explanation of specific violations noted, refer to remarks section of inspection report

REL	WNN	REL	WNN	REL	WNN
1				10	
2		15		35	✓
3		60		67	
4		68		21	
5	✓	31		22	
6		17		82	
7		18		83	
8		46		84	
9		54		16	
36		24		27	
39		30	✓	51	
38		86		75	
43	✓	19		70	
47		25		71	
48		32		72	
53		40		81	
57		26		85	
59		37	✓	87	
61		45		88	
62		44		89	
65		55		28	
68		78		29	
76		80		52	
34	✓	56		63	
79		50		64	
90	✓	49		91	
92		33		73	



Transcript:

Remarks

- Code 0102: Ensure reference library is available to all RPhs
- Code 1902: Ensure proper written controlled substance prescriptions bear the prescriber's manual signature. Ensure prescriptions carried out by NP/PA, bear name of NP/PA & their supervising physician, and if a c/s both DEA #s.
- Code 2102: Ensure all dispensing RPhs are individually logged.
- Code 2602: Ensure documentation of initial tech training is available for each technician.
- Code 2802: Ensure staff use a nail cleaner.
- Code 28402: Ensure staff apply alcohol scrub to hands prior to donning sterile gloves over inside buffer room.
- Code 2902: Cleaning log shall bear time and each cleaning.
- Code 4602: Ensure written agreements are available for both Pharmacist/Vet.

Action Taken

See Warning Notices

- (1) ☒ Inspection
- (2) ☐ Pre-Inspection
- (3) ☐ Partial Inspection
- (4) ☐ Visit
- (5) ☐ Other \_\_\_\_\_

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

1/10/2018

Date

Time of Exit

Printed Name and Title of Authorized Individual

Dr. David P. Miller, President

09/12

Texas State Board of Pharmacy

last page





**ARL BIO PHARMA**  
 840 RESEARCH PARKWAY, SUITE 546  
 OKLAHOMA CITY, OK 73104  
 PHONE (405) 271-1144  
 FAX (405) 271-1174

## Certificate Of Analysis

**CLIENT:** Astell Rite-Value Pharmacy, Inc.  
 304 1/2 Charlie Drive  
 Whitesboro, TX 76273

*made on 12-8-16*  
*Exp date 1-7-17*  
*before test results*

**ARL #:** 392811-01

**LOT #:** 677285323

**DESCRIPTION:** Tropicamide/Phenylephrine 1%/2.5% Opth Solution

**DATE RECEIVED:** 02/01/2017

**STORAGE:** 20°C to 25°C (68°F to 77°F)

**CONTAINER:** Two 3 mL dropper bottles w/3 mL each in a brown bag

*(With Exp)*  
*before test results*

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Phenylephrine HCl Specifications = 90% - 115%	2.5	%	2.464	98.6%	HPLC	2/2/2017
Tropicamide Specifications = 90% - 110%	1.0	%	0.9726	97.3%	HPLC	2/6/2017

The analyses referenced in this report are for non-cGMP purpose only. The method(s) used for testing are not validated. Specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

*WTY*

Wen Yang - Chemist

02/06/2017

Date Reported

ARL Form QLF-078-V4 03/05/2010

## Logged Formula Worksheet

01/09/2018 2:53:22 PM

Page 1


 AXTELL-RITE VALUE PHARMACY  
 304 1st Chance Dr. PO BOX 9  
 WHITEBORO, TX 76273 PH: (800) 554-3216

## TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Tall Man

 Flavor:  
 Quantity made: 15 ML

 Batch yield: 15 000  
 Qty remaining: 15 000

 Schedule:  
 PCCA ID  
 Route of admin:
NIOSH Hazard ☐
 Active ☒  
 Formula ID: 0172  
 Log ID: 00007

 Date made: 12/08/2016  
 Lot number: 12082016@21  
 Beyond use date: 01/07/2017 5:44 PM  
 60 days after compounding date

 Pharmacist: TOM AXTELL  
 Technician: SEE INITIALS  
 Misc. Note:  
 NDC1:

 Description:  
 Packaging:  
 Equipment:

Time to make: 0

Picture

 Labeling:  
 Stability information:

Chemicals	NIOSH Hazard	Schedule	Quantity used	QS (balance)
1 TROPICAMIDE USP POWDER	<input type="checkbox"/>	L	0.15 GM	<input type="checkbox"/>
Lot #: 114419/F Hazard code: H 1	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 1808-75-4 Stock: 1.101	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			QS amount:	Each ML contains 0.01 GM or 1%
			NDC:	
2 PHENYLEPHRINE HCL USP POWDER	<input type="checkbox"/>		0.375 GM	<input type="checkbox"/>
PHENYLEPHRINE HCL Lot #: 1506150019 Hazard code: -	Mfg: LETCO Volume: Potency:	CAS: 1506-150019 Stock: 15.25	Whlar: LETCO COMPANIES ChemInvID: 0	NDC
Balance info: Purity:			QS amount:	Each ML contains 0.025 GM or 2.5%
			NDC:	
3 SODIUM METABISULFITE 1% (W/V) WATER FOR IN	<input type="checkbox"/>		1.5 ML	<input type="checkbox"/>
Lot #: 012345 Hazard code: H F PH PR	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 515 Stock: 515	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			QS amount:	Each ML contains 0.1 ML or 10%
			NDC:	
4 EDETATE DISODIUM 1% (W/V) WATER FOR INJEC	<input type="checkbox"/>		0.75 ML	<input type="checkbox"/>
Lot #: 85747 Hazard code: H F PH PR	Mfg: MEDISCA, INC. Volume: Potency:	CAS: 49.25 Stock: 49.25	Whlar: MEDISCA, INC. ChemInvID: 0	NDC
Balance info: Purity:			QS amount:	Each ML contains 0.05 ML or 5%
			NDC:	
5 BENZALKONIUM CHLORIDE 1% (W/V) WATER FOR	<input type="checkbox"/>		0.3 ML	<input type="checkbox"/>
Lot #: C148206 Hazard code: H F PH PR	Mfg: PROFESSION Volume: Potency:	CAS: 85.075 Stock: 85.075	Whlar: PROFESSIONAL COMPOUN ChemInvID: 0	NDC
Balance info: Purity:			QS amount:	Each ML contains 0.02 ML or 2%
			NDC:	

 Date entered: 12/08/2016 5:44:19 PM Last modified: 01/09/2018 2:55:33 PM by: AXTELL TOM/SEE INITIALS.  
 Checked by: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

## Logged Formula Worksheet

01/09/2018 2:53:22 PM

Page 2



AXTELL/RITE VALUE PHARMACY

304 1/2 Charlie Dr. PO BOX 9

WHITESBORO, TX 76273 Ph: (803) 564-3216

TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Tab Man:

Flavor:  
Quantity made: 15 MLBatch yield: 15 000  
Qty remaining: 15 000Schedule  
PCCA IDNIOSH Hazard ☐Active ☒  
Formula ID: 6772  
Log ID: 66323

Route of admin:

## Chemicals NIOSH Hazard Schedule Quantity used QS (balance)

1 HYDROCHLORIC ACID 10% INJECTABLE ☐ 0.15 GTTS ☐  
 Lot # N/A CAS [REDACTED] Stock 102 973 8113 NDC  
 Hazard code: H F PH PR Volume: [REDACTED] Whisker STORE  
 Polency: [REDACTED] ChemInviD0  
 Purity: [REDACTED]  
 Balance info: [REDACTED] Each ML contains 0.01 GTTS or 0.05%  
 NDC

2 SODIUM HYDROXIDE 10% SOLUTION SOLUTION ☐ 0.15 GTTS ☐  
 Lot # N/A CAS [REDACTED] Stock 1 018 667 561 82 NDC  
 Hazard code: H F PH PR Volume: [REDACTED] Whisker Store  
 Polency: [REDACTED] ChemInviD0  
 Purity: [REDACTED]  
 Balance info: [REDACTED] Each ML contains 0.01 GTTS or 0.05%  
 NDC

3 WATER (STERILE FOR INJECTION) INJECTABLE ☐ 15 ML ☒  
 Lot # 26-070-JT CAS [REDACTED] Stock 28 498 6398 NDC  
 Hazard code: H F PH PR Volume: [REDACTED] Whisker PROFESSIONAL COMPOUN  
 Polency: [REDACTED] ChemInviD0  
 Purity: [REDACTED]  
 Balance info: [REDACTED] Each ML contains 1 ML or 100%  
 NDC

## Log Instructions &amp; Notes

Originally made as: 15 TROPICAMIDE/PHENYLEPHRINE HCL 1%/2.5% OPTH SOLUTIO

Calculated lot number: 12082018@21 Beyond use date: 01/07/2017

## FORMULA INSTRUCTIONS

- 1 Dissolve Phenylephrine in Water for injection, (Use approximately 70% of water for injection)
- 2 Adjust the pH to 4-4.5 with hydrochloric acid or sodium hydroxide
- 3 Dissolve Tropicamide in Step 2
- 4 Add Sodium Metabisulfite 1%, Edetate Disodium 1% and Benzalkonium Chloride 1% to Step 3 & mix well
- 5 Adjust the pH to 4-4.5
- 6 Bring to final volume with water for injection and mix thoroughly
- 7 Filter with a 0.22 micron filter and place in sterile droptainer

\*\*\* PROTECT FROM LIGHT &amp; STORE ROOM TEMP\*\*\*

Date entered: 12/08/2016 5:44:19 PM Last modified: 01/09/2018 2:55:33 PM by: AXTELL, TOM/SEE INITIALS.

Checked by: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509  
**APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE**

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: **PH 03548**)  
 Check box below for type of ownership and complete all required forms.  
☐ Publicly Traded Corporation – Pages 1,2,3,7      ☐ Partnership – Pages 1,2,5,7  
☒ Non Publicly Traded Corporation – Pages 1,2,4,7      ☐ Sole Owner – Pages 1,2,6,7

**GENERAL INFORMATION to be completed by all types of ownership**

Pharmacy Name: Braun Pharma, LLC  
 Physical Address: 2060 N. Clark St., Chicago IL 60614  
 Mailing Address: 2060 N. Clark St.  
 City: Chicago State: Illinois Zip Code: 60614  
 Telephone: 773-549-0634 Fax: 773-549-2753  
 Toll Free Number: 877-549-6907 (Required per NAC 639.708)  
 E-mail: braundrug@aol.com Website: www.braunrx.com  
 Managing Pharmacist: Sharron Seymour License Number: 051.289557

**TYPE OF PHARMACY AND SERVICES PROVIDED**

Yes/No

- ☒ ☐ Retail  
☐ ☒ Hospital (# beds \_\_\_\_)  
☐ ☒ Internet  
☐ ☒ Nuclear  
☐ ☒ Ambulatory Surgery Center  
☐ ☒ Community  
☐ ☐ Other: \_\_\_\_\_

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services  
☐ ☒ Parenteral \*\*  
☐ ☒ Parenteral (outpatient)  
☐ ☒ Outpatient/Discharge  
☒ ☐ Mail Service  
☐ ☒ Long Term Care  
☒ ☐ Sterile Compounding \*\*  
☒ ☐ Non Sterile Compounding  
☒ ☐ Mail Service Sterile Compounding \*\*  
☐ ☒ Other Services: \_\_\_\_\_

**\*\*If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**



# APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

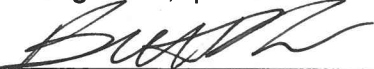
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Brett Pine

Print Name of Authorized Person

5-30-2018

Date

Page 2

Board Use Only

Date Processed: \_\_\_\_\_

Amount: \$500.00



## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**

State of Incorporation: Illinois  
 Parent Company if any: Optio Rx, LLC - 100% Member  
 Mailing Address: 2060 N. Clark St.  
 City: Chicago State: Illinois Zip: 60614  
 Telephone: 773-549-0634 Fax: 773-549-2753  
 Contact Person: Sharron Seymour

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation? N/A - LLC
  - a) N/A - LLC  

Name
Address
  - b) \_\_\_\_\_  

Name
Address
  - c) \_\_\_\_\_  

Name
Address
  - d) \_\_\_\_\_  

Name
Address
- 2) Provide the number of shares issued by the corporation. N/A - LLC
- 3) What was the price paid per share? N/A - LLC
- 4) What date did the corporation actually receive the cash assets? N/A - LLC
- 5) Provide a copy of the corporation's stock register evidencing the above information

List any physician shareholders and percentage of ownership.

Name: N/A - LLC %: \_\_\_\_\_  
 Name: N/A - LLC %: \_\_\_\_\_

**Hours of Operation for the pharmacy:**

Monday thru Friday <u>9</u> am <u>7</u> pm	Saturday <u>9</u> am <u>4</u> pm
Sunday <u>Closed</u> am <u>Closed</u> pm	24 Hours <u>N/A</u>

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: \_\_\_\_\_

STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, Brett Pine

Responsible Person of Braun Pharma, LLC

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Brett Pine

Print Name of Authorized Person

5-30-2018

Date

# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF Illinois )  
Cook ) ss.  
COUNTY )

I, Brett Pine, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President for Braun Pharma, LLC (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Brett Pine, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

SUBSCRIBED AND SWORN TO  
before me, a notary public this  
30 day of May, 2018.

Christine M. Solorio  
NOTARY PUBLIC

Brett Pine  
Name

*Brett Pine*





## Braun Pharma, LLC

### Officers:

Brett Pine – President  
2060 N. Clark Street, Chicago, IL 60614

### Owners:

OptioRX, LLC – 100% Member  
1247 Waukegan Rd, Glenview, IL 60015

**NEVADA STATE BOARD OF PHARMACY**  
 431 W Plumb Lane – Reno, NV 89509  
**APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE**

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☒ **Ownership Change** (Provide current license number if making changes: PH 02236  
 Check box below for type of ownership and complete all required forms.  
☐ Publicly Traded Corporation – Pages 1,2,3,7      ☐ Partnership - Pages 1,2,5,7  
☒ Non Publicly Traded Corporation – Pages 1,2,4,7      ☐ Sole Owner – Pages 1,2,6,7

**GENERAL INFORMATION to be completed by all types of ownership**

Pharmacy Name: Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs

Physical Address: 7631 E. Indian School Road Ste. 105, Scottsdale, AZ 85251

Mailing Address: Same as above

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Telephone: 480-946-2223 Fax: 866-646-2235

Toll Free Number: 866-646-2223 (Required per NAC 639.708)

E-mail: kory.muto@diamondbackdrugs.com Website: www.diamondbackdrugs.com

Managing Pharmacist: Kory Muto License Number: AZ--S020692

**TYPE OF PHARMACY AND**

**SERVICES PROVIDED**

Yes/No

- ☒ ☐ Retail  
☐ ☒ Hospital (# beds \_\_\_\_\_)  
☐ ☒ Internet  
☐ ☒ Nuclear  
☐ ☒ Ambulatory Surgery Center  
☐ ☒ Community  
☒ ☐ Other: Veterinary

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services  
☐ ☒ Parenteral \*\*  
☐ ☒ Parenteral (outpatient)  
☐ ☒ Outpatient/Discharge  
☒ ☐ Mail Service  
☐ ☒ Long Term Care  
☒ ☐ Sterile Compounding \*\*  
☒ ☐ Non Sterile Compounding  
☒ ☐ Mail Service Sterile Compounding \*\*  
☐ ☒ Other Services: \_\_\_\_\_

**\*\*If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

## APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

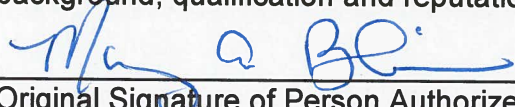
Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

**If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached.** Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.



Original Signature of Person Authorized to Submit Application, no copies or stamps

\_\_\_\_\_  
 Marcy Bliss  
 Print Name of Authorized Person

6/7/18  
 Date

Page 2

Board Use Only

Date Processed: \_\_\_\_\_

Amount: \$500.00



## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**

State of Incorporation: Delaware

Parent Company if any: See attached. (Owner/Officer information)

Mailing Address: 405 Heron Drive, Suite 200

City: Swedesboro State: NJ Zip: 08085

Telephone: 800-331-8272 Fax: 856-832-1431

Contact Person: Marcy Bliss - CEO/President/Secretary/Treasurer

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?
  - a) N/A  

Name
Address
  - b) N/A  

Name
Address
  - c) N/A  

Name
Address
  - d) N/A  

Name
Address
- 2) Provide the number of shares issued by the corporation. N/A
- 3) What was the price paid per share? N/A
- 4) What date did the corporation actually receive the cash assets? N/A
- 5) Provide a copy of the corporation's stock register evidencing the above information

\*\*Not applicable

List any physician shareholders and percentage of ownership.

Name: None. %:

Name:  %:

**Hours of Operation for the pharmacy:**

Monday thru Friday 6 am 7 pm                      Saturday 7 am 2 pm

Sunday N/A am  pm                      24 Hours N/A

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

**Must be included with the application for a non publicly traded corporation**

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

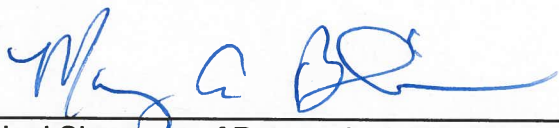


STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I,     Marcy Ann Bliss      
Responsible Person of     Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs      
hereby acknowledge and understand that in addition to the corporation's, any owner(s),  
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law  
that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)  
or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a  
pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)  
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision  
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.



Original Signature of Person Authorized to Submit Application, no copies or stamps

    Marcy Ann Bliss - CEO/President/Treasurer/Secretary    

Print Name of Authorized Person

    6/7/18    

Date

# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF \_\_\_\_\_ )  
 ) ss.  
 \_\_\_\_\_ COUNTY )

I, Marcy Ann Bliss, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO/President/Treasurer/ for Wedgewood Village Pharmacy, (the Secretary LLC d/b/a Diamondback Drugs Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

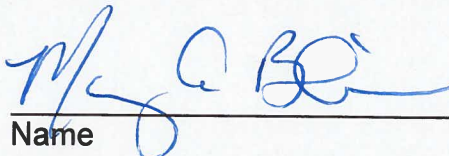
3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, Marcy Ann Bliss, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

  
 Name

SUBSCRIBED AND SWORN TO  
 before me, a notary public this  
7 day of June, 2018.

  
 NOTARY PUBLIC

BRIDGETTE A CONNOR  
 Commission # 50048680  
 Notary Public, State of New Jersey  
 My Commission Expires  
 October 31, 2021



# CORPORATE OWNER/OFFICER INFORMATION

## WEDGEWOOD VILLAGE PHARMACY, LLC CORPORATE INFORMATION

On or about July 31, 2018, Wedgewood Village Pharmacy Intermediate Holdings, LLC (“*Wedgewood Holdings*”) will purchase all of the issued and outstanding stock of TW Diamondback Holdings Corp. (the “*Company*”). The Company owns 100% of the limited liability company interests of Diamondback Drugs of Delaware, L.L.C. (“*Diamondback Drugs*”), which operates a traditional compounding pharmacy in Scottsdale, Arizona. In connection with the stock purchase, Diamondback Drugs will merge into Wedgewood Village Pharmacy, LLC (“*Wedgewood*”), a subsidiary of Wedgewood Holdings, and all of Diamondback Drugs’ assets, liabilities and operations will become vested in Wedgewood, and the separate existence of Diamondback Drugs shall cease. Wedgewood will continue to operate Diamondback Drugs as Wedgewood Village Pharmacy, LLC d/b/a Diamondback Drugs. Wedgewood will also continue to operate its pharmacy, Wedgewood Pharmacy, in Swedesboro, NJ. The ownership structure of Wedgewood Village Pharmacy, LLC after this transaction will be as follows:

Wedgewood Village Pharmacy, LLC will have two members:

1. Wedgewood Village Pharmacy Intermediate Holdings, LLC (56.5%)

c/o New Harbor Capital  
500 West Madison, Suite 2830  
Chicago, IL 60661  
(312) 876-8605

2. TW Diamondback Holdings Corp. (43.5%)

c/o Tailwind Management LP  
485 Lexington Avenue, 23rd Floor  
New York, NY 10017  
(212) 271-3800

*\*all stock of TW Diamondback Holdings Corp. is held by Wedgewood Village Pharmacy Intermediate Holdings, LLC.*

Wedgewood Village Pharmacy, LLC will have the following four officers:

1. Marcy Ann Bliss

CEO, President, Treasurer and Secretary

2. Thomas Joseph Formolo

Assistant Secretary



3. Jocelyn Rose Stanley

Assistant Secretary

4. Edward Michael Lhee

Assistant Secretary

RESPONSE TO DISCIPLINARY  
QUESTION #3



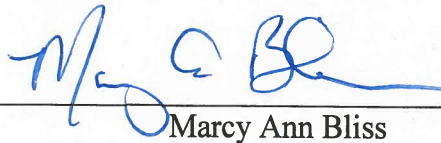
*Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry?*

First, Wedgewood Village Pharmacy, LLC ("*Wedgewood*") wishes to clarify that the answer to this question is "No" with respect to Diamondback Drugs of Delaware, LLC, which currently holds the license that is the subject of this change-of-ownership application, and its compounding pharmacy in Scottsdale, Arizona. However, because Wedgewood currently operates another compounding pharmacy in Swedesboro, New Jersey called Wedgewood Pharmacy, out of an abundance of caution and in the interest of full disclosure, Wedgewood wishes to divulge the following related to its other facility in New Jersey:

On March 19, 2015, Wedgewood finalized a consent order with the Minnesota Board of Pharmacy ("*Minnesota Consent Order*"), a copy of which is attached hereto. Wedgewood subsequently entered into consent orders with the Michigan Department of Licensing and Regulatory Affairs ("*Michigan LARA*") and the Alabama Board of Pharmacy ("*Alabama BOP*") to resolve "sister state" actions that arose out of the Minnesota Consent Order. The Michigan and Alabama consent orders are attached hereto.

The facts underlying the Minnesota Consent Order are as follows. Acting on a reasonable and good-faith interpretation of Minnesota law, Wedgewood dispensed compounds to licensed veterinarians in Minnesota, pursuant to a veterinarian's order for office use. The Minnesota Board asserted that Wedgewood needed a wholesale license to engage in this activity. For the purposes of settlement only, Wedgewood entered into the Minnesota Consent Order whereby it agreed to a \$10,000 civil penalty but admitted no wrongdoing. Wedgewood subsequently entered into a consent order with the Michigan LARA to resolve a "sister state" action brought by Michigan based on the Minnesota Consent Order. Wedgewood entered into a similar consent order with the Alabama BOP to resolve a sister state action brought by Alabama based on the Minnesota Consent Order. There was no finding in the Michigan or the Alabama consent order that Wedgewood violated any provisions of Michigan or Alabama state law outside of these states' prohibition on "sister state" actions.

Finally, on February 27, 2018, Wedgewood was issued an administrative citation and a \$1,000 fine as a result of an investigation by the California Board of Pharmacy (the "*California Board*"). The citation is not a discipline by the California Board and payment of the fine does not constitute any admission of any wrongdoing by Wedgewood. A copy of the citation is attached hereto.

  
\_\_\_\_\_  
Marcy Ann Bliss

Date: 6/2/18



# MINNESOTA BOARD OF PHARMACY

*An Equal Opportunity Employer*

2829 University Ave. SE, #530 • Minneapolis, MN 55414-3251 • Telephone: (651) 201-2825 • FAX: (651) 201-2837

MN RELAY SERVICE FOR HEARING/SPEECH IMPAIRED ONLY:

Metro and Non-Metro; 800-627-3529

E-Mail Address: [Pharmacy.Board@state.mn.us](mailto:Pharmacy.Board@state.mn.us)

Web Site: [www.pharmacy.state.mn.us](http://www.pharmacy.state.mn.us)

MAR 19 2015

PERSONAL & CONFIDENTIAL

March 16, 2015

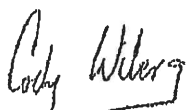
Gregory P. Bulinski  
Attorney  
Bassford Remele  
33 South Sixth Street, Suite 3800  
Minneapolis, MN 55402-3707

Re: In the Matter of Wedgewood Pharmacy  
License No. 262173

Dear Mr. Bulinski,

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent issued by the Board of Pharmacy.

Sincerely,



Cody Wiberger, Pharm D, MS, RPh  
Executive Director



BEFORE THE MINNESOTA  
BOARD OF PHARMACY

In the Matter of  
Wedgewood Pharmacy, Non-Resident Pharmacy  
License Number: 262173

STIPULATION AND  
CONSENT ORDER

STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.

2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Goetz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Bassford Remele and Rachael G. Pontilces, Esq., of Duane Morris.

### III.

#### FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

### IV.

#### ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

## V.

## DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

## VI.

## CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.



b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

## VII.

### ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

#### VIII.

##### DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.



CONSENT:

BOARD OF PHARMACY  
COMPLAINT REVIEW PANEL

M. Bliss  
MARCY BLISS, PRESIDENT  
Wedgewood

Dated: 1/13/15

Karen Bergrud  
KAREN BERGRUD  
Board Member

Dated: 1/21/2015

ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21<sup>st</sup> day of January, 2015.

MINNESOTA BOARD  
OF PHARMACY

Cody Wiberg

CODY WIBERG  
Executive Director

IN THE MATTER OF:

WEDGEWOOD VILLAGE PHARMACY,  
LLC

Non-Resident Pharmacy  
Permit Number: 112625

BEFORE THE ALABAMA STATE  
BOARD OF PHARMACY

CASE NO: 16-L-0066

### CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Wedgewood Village Pharmacy, LLC ("Wedgewood") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as Exhibit "A."

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Wedgewood through its counsel engaged in negotiations and as a result the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Wedgewood has violated the "sister-state" provisions of Alabama law as set out in the Statement of Charges.
2. Wedgewood shall pay an administrative fine in the amount of Three Thousand Dollars (\$3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall either pharmacy attempt to discharge the same.
3. Wedgewood expressly waive its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975),

§34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Wedgewood further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Wedgewood hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Wedgewood acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Wedgewood's permit, including, but not limited to revocation.

6. Wedgewood acknowledges and agrees that it has read this Consent Order and that it fully understand the terms, conditions and contents of the same. Wedgewood acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.



DONE this the 6th of June, 2017.

WEDGEWOOD VILLAGE PHARMACY, LLC

BY: Mr. A. B.

ITS: President & CEO

Jennifer Clark  
Jennifer Clark, attorney for Wedgewood Village  
Pharmacy, LLC

DONE this the \_\_\_\_\_ of 6/13/2017, 2017.

ALABAMA STATE BOARD OF PHARMACY

Buddy Bunch  
By: Buddy Bunch, R.Ph., President

James S. Ward  
By: James S. Ward,  
Attorney for the Alabama State  
Board of Pharmacy

**OF COUNSEL:**  
**WARD & WILSON, LLC**  
2100A Southbridge Parkway  
Suite 580  
Birmingham, AL 35209  
(205) 871-5404

# EXHIBIT "A"

IN THE MATTER OF:

WEDGEWOOD VILLAGE PHARMACY,  
LLC

Non-Resident Pharmacy  
Permit Number: 112625

BEFORE THE ALABAMA STATE  
BOARD OF PHARMACY

CASE NO: 18-L-0086

## STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Wedgewood Village Pharmacy, LLC  
405 Heron Drive  
Suite 200  
Swedesboro, New Jersey 08085

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12), Code of Alabama (1975), §20-2-213(e) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on \_\_\_\_\_, 2016 at \_\_\_\_\_ m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Wedgewood Village Pharmacy, LLC (Wedgewood) should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Wedgewood has been guilty of the following, to-wit:

### COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of a Stipulation and Consent Order by the Minnesota Board of Pharmacy on January 4,

2015 attached hereto as Exhibit "A" and/or the Facts set out therein that you shipped drugs to licensed veterinarians in Minnesota without patient specific prescriptions nor the required license to do so.

**COUNT TWO**

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

**COUNT THREE**

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon the Consent Order entered by the State of Michigan Board of Pharmacy on April 13, 2016 as a result of the filing of an Administrative Complaint, these documents being attached hereto as Exhibits "B" and "C".

Further, pursuant to the provisions of Code of Alabama, (1975), §20-2-53 and §41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), §20-2-1, et. seq., issued pursuant to Code of Alabama (1975), §20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

**COUNT FOUR**

Violating Code of Alabama (1975), §20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), §34-23-1 et seq., said violation being based upon any or all of



the allegations contained in the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney. If you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the \_\_\_\_\_ day of \_\_\_\_\_, 2016.

ALABAMA STATE BOARD OF PHARMACY

By: \_\_\_\_\_  
Susan Alverson  
Secretary

# EXHIBIT "A"

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of  
Wedgewood Pharmacy, Non-Resident Pharmacy  
License Number: 262173

STIPULATION AND  
CONSENT ORDER

## STIPULATION

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

### I.

#### JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.
2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

### II.

#### CONFERENCE

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Berglund and Bob Goeitz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bulinski, Esq., of Hartford Remick and Rachel O. Fontikes, Esq., of Duane Morris.

### III. FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2013, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

### IV. ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing" in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(ix) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.



## V.

**DISCIPLINARY ACTION**

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board impose a **CIVIL PENALTY** in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wilberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

## VI.

**CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS**

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

#### VII.

#### ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

### VIII.

#### DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 3. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.



## CONSENT:

BOARD OF PHARMACY  
COMPLAINT REVIEW PANEL

M. B.  
MARCY BLISS, PRESIDENT  
Wedgewood

Karen Bergrud  
KAREN BERGRUD  
Board Member

Dated: 1/13/15

Dated: 1/21/2015

## ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and  
adopts all of the terms described above on this 21<sup>st</sup> day of January  
2015.

MINNESOTA BOARD  
OF PHARMACY

Cody Wiberg

CODY WIBERG  
Executive Director

**EXHIBIT "B"****BEFORE THE MINNESOTA  
BOARD OF PHARMACY**

In the Matter of  
Wedgewood Pharmacy, Non-Resident Pharmacy  
License Number: 262173

**STIPULATION AND  
CONSENT ORDER****STIPULATION**

Wedgewood Pharmacy ("Pharmacy" or "Licensee") and the Minnesota Board of Pharmacy Complaint Review Panel ("Review Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

**I.****JURISDICTION**

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to register and regulate pharmacies and to take disciplinary action as appropriate.
2. Wedgewood has been licensed as a non-resident pharmacy in Minnesota since October 22, 2002. As such, Wedgewood is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

**II.****CONFERENCE**

3. On December 4, 2013, Wedgewood representatives attended a conference with the Review Panel to discuss the allegations described in a Notice of Conference. The Review Panel was composed of Board members Karen Bergrud and Bob Gotsz. Bryan D. Huffman, Assistant Attorney General, represented the Review Panel in this matter. Wedgewood was represented by Greg Bullinski, Esq., of Bassford Remole and Rachael O. Pontikes, Esq., of Duane Morris.

EXHIBIT A page 1 of 2

## III.

## FACTS

4. Licensee is not, nor has it ever been, licensed as a drug wholesaler by the Board.
5. Licensee shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions.
6. Beginning January 7, 2012, Licensee dispensed drugs only pursuant to patient-specific prescriptions.

## IV.

## ISSUES

7. Licensee asserts it was acting on a good-faith interpretation of Minnesota law when it shipped drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. Minn. Stat. § 151.01, subd. 30 (2012) defined "dispense or dispensing," in part, as meaning "the preparation or delivery of a drug pursuant to a lawful order. . . ." Licensee asserts that it reasonably and in good faith interpreted "lawful order" to include an order by a veterinarian for office use.

8. The Board asserts that Licensee's conduct described in section III. above constitutes violations of Minn. Stat. §§ 151.06, subd. 1(a)(7)(b) and 151.47, subd. 1(b). The Board asserts that Minnesota law at all times relevant hereto prohibited Licensee from shipping drugs for office use without being licensed as a wholesaler.

9. For purposes of the settlement of this matter only, and for no other purposes civil, administrative or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

## V.

## DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

10. The Board imposes a CIVIL PENALTY in the amount of \$10,000 for the conduct described in section III above. The civil penalty must be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.

## VL

## CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

11. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Review Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Review Panel must schedule a hearing before the Board. At least 20 days before the hearing, the Review Panel must mail Licensee a notice of the violation(s) alleged by the Review Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee must submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.



b. The Review Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Review Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Review Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Review Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations but may present argument concerning the appropriateness of additional discipline. Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but will not limit the Board's authority to impose discipline for the violation. A decision by the Review Panel not to seek discipline when it first learns of a violation shall not waive the Review Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's registration is in a conditional status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's future practice or suspension or revocation of Licensee's registration.

f. Nothing herein limits the Review Panel's or the Board's right to temporarily suspend Licensee's license pursuant to Minnesota Statutes section 151.06, subdivision 1(b), based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

#### VII.

#### ADDITIONAL INFORMATION

12. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

13. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

14. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter will constitute the entire record and may be reviewed by the Board in its consideration of this matter.

15. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

16. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order

will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

17. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.

18. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

#### VIII.

##### DATA PRACTICES NOTICES

19. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed person, and as such, is classified as protected nonpublic data pursuant to Minnesota Statutes sections 13.39, subdivision 2, and 13.02, subdivision 13.

20. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

## CONSENT:

BOARD OF PHARMACY  
COMPLAINT REVIEW PANEL

M. BO  
MARCY BLESS, PRESIDENT  
Wedgewood

Karen Bergerud  
KAREN BERGRUD  
Board Member

Dated: 1/13/15

Dated: 1/21/2015

## ORDER

Upon consideration of the Stipulation, the Board imposes a CIVIL PENALTY, and adopts all of the terms described above on this 21<sup>st</sup> day of January, 2015.

MINNESOTA BOARD  
OF PHARMACY

Cody Wiberg  
CODY WIBERG  
Executive Director



By signing this stipulation, the parties confirm that they have read,  
understand and agree with the terms of the consent order,

AGREED TO BY:

Kelly K. Elzondo  
Kelly K. Elzondo (B45534)  
Assistant Attorney General  
Attorney for Complainant  
Dated: 5-1-2016

AGREED TO BY:

Alison Lylich  
Alison Lylich, Pharmacist-in-Charge  
Wedgewood Village Pharmacy  
Respondent  
Dated: 5/31/16

Alan T. Rogalski  
Alan T. Rogalski (B44580)  
Attorney for Respondent  
Dated: 5/31/2016

## EXHIBIT "C"

STATE OF MICHIGAN  
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
BUREAU OF HEALTH CARE SERVICES  
BOARD OF PHARMACY  
DISCIPLINARY SUBCOMMITTEE

In the matter of

WEDGEWOOD VILLAGE PHARMACY INC.  
License Number: 53-01-008041

File Number: 53-15-137238

### ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs (Complainant) by Kim Gaedeke, Acting Director, Bureau of Health Care Services, files this Complaint against Wedgewood Village Pharmacy Inc. (Respondent Pharmacy) as follows:

1. The Michigan Board of Pharmacy (Board) is an administrative agency established by the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq. Pursuant to section 17768 of the Public Health Code, supra, the Board's Disciplinary Subcommittee is empowered to discipline licensees for violations of the Public Health Code.
2. Respondent Pharmacy is licensed to practice as a pharmacy in the state of Michigan and has an address of record with Complainant of Swedesboro, New Jersey.
3. On January 21, 2015, the Minnesota Board of Pharmacy (Minnesota Board) executed a Stipulation and Consent Order which ordered Respondent Pharmacy

to pay a \$10,000.00 civil penalty. The action was based on Respondent Pharmacy not being licensed as a drug wholesaler by the Minnesota Board and shipping drugs to licensed veterinarians in Minnesota without patient-specific prescriptions. A copy of the Stipulation and Consent Order, marked Exhibit A, is attached and incorporated

#### COUNT I

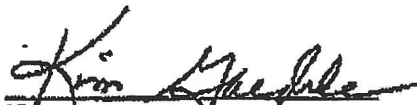
The action by the Minnesota Board, as set forth above evidence a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended, or revoked, or been subject to any other criminal, civil, or administrative penalty and constitutes a violation of section 17768(2)(d) of the Public Health Code, supra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license. If compliance is not shown, Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code, rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq.

Pursuant to section 16231(8) of the Public Health Code, supra, Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Kim Gaedeke, Acting Director, Bureau of Health Care Services, Department of Licensing and Regulatory Affairs, P.O. Box 30870, Lansing, MI 48909.

Pursuant to section 16231(9) of the Public Health Code, supra, Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this Complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 07/24/2015

  
Kim Gaedake, Acting Director  
Bureau of Health Care Services

Attachment

This is the final page of an Administrative Complaint in the matter of Wedgewood Village Pharmacy Inc., File Number 53-16-137238, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

DWC



STATE OF MICHIGAN  
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS  
BUREAU OF PROFESSIONAL LICENSING  
BOARD OF PHARMACY  
DISCIPLINARY SUBCOMMITTEE

In the Matter of

WedgeWood Village Pharmacy, Inc.      Complaint No. 53-15-137238  
License No. 53-01-008041

CONSENT ORDER AND STIPULATION

CONSENT ORDER

An administrative complaint was filed with the Disciplinary Subcommittee of the Board of Pharmacy on July 24, 2015, charging Wedgewood Village Pharmacy, Inc. (Respondent) with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended, MCL 333.1101 *et seq.*

The parties have stipulated that the Disciplinary Subcommittee may enter this consent order. The Disciplinary Subcommittee has reviewed the stipulation contained in this document and agrees that the public interest is best served by resolution of the outstanding complaint. Therefore, the Disciplinary Subcommittee finds that the allegations of fact contained in the complaint are true and that Respondent has violated section 17768(2)(d) of the Public Health Code.

Accordingly, for this violation, IT IS ORDERED:

Respondent is FINED \$500.00 (Five Hundred Dollars) to be paid by check, money order or cashier's check made payable to the State of Michigan (with complaint number 53-15-137238 clearly indicated on the check or money order), and

shall be payable within 60 days of the effective date of this order. The timely payment of the fine shall be Respondent's responsibility. Respondent shall mail the fine to: Sanction Monitoring, Bureau of Professional Licensing, Enforcement Division -- Compliance Section, Department of Licensing and Regulatory Affairs, P.O. Box 30189, Lansing, Michigan 48909.

This order shall be effective on the date signed by the Chairperson of the Disciplinary Subcommittee or the Disciplinary Subcommittee's authorized representative, as set forth below.

Signed on 4-13-16

MICHIGAN BOARD OF PHARMACY

By   
Chairperson, Disciplinary Subcommittee

STIPULATION

The parties stipulate as follows:

1. Respondent does not contest the allegations of fact and law in the complaint. Respondent understands that, by pleading no contest, it does not admit the truth of the allegations but agrees that the Disciplinary Subcommittee may treat the allegations as true for resolution of the complaint and may enter an order treating the allegations as true.
2. Respondent understands and intends that, by signing this stipulation, it is waiving the right under the Public Health Code, rules promulgated under the Public Health Code, and the Administrative Procedures Act of 1969, 1969 PA 306,

as amended, MCL 24.201 *et seq.*, to require the Department to prove the charges set forth in the complaint by presentation of evidence and legal authority, and to present a defense to the charges before the Disciplinary Subcommittee or its authorized representative. Should the Disciplinary Subcommittee reject the proposed consent order, the parties reserve the right to proceed to hearing.

3. The Disciplinary Subcommittee may enter the above Consent Order, supported by Board conferee Patti Smeelink, R.Ph. Ms. Smeelink or an attorney from the Licensing and Regulation Division may discuss this matter with the Disciplinary Subcommittee in order to recommend acceptance of this resolution.

4. Conferee Smeelink and the parties considered the following factors in reaching this agreement:

- A. Respondent has fully cooperated in this matter and since initially licensed in 2004, Respondent has never had any disciplinary action taken against its Michigan Pharmacy license prior to this incident.
- B. Respondent timely reported the Minnesota Board of Pharmacy Stipulation and Consent Order to the Department.
- C. The violation of MCL 333.17768(d)(2) as alleged in the Complaint is based solely on a "sister-state" action taken against Respondent's Pharmacy license by the Minnesota Board of Pharmacy that was based on Respondent's former practice in 2012 of dispensing compounded veterinary medications for office-use to licensed veterinarians in Minnesota, which according to the Minnesota Board of Pharmacy, required a wholesaler's license. However, this practice did not implicate Respondent's practice of pharmacy in the State of Michigan and Respondent has not been found to have violated the Michigan Public Health Code or Board of Pharmacy Administrative Rules, except as provided herein.

By signing this stipulation, the parties confirm that they have read,  
understand and agree with the terms of the consent order,

AGREED TO BY:

AGREED TO BY:

Kelly K. Elizondo  
Kelly K. Elizondo (P45534)  
Assistant Attorney General  
Attorney for Complainant  
Dated: 3-1-2016

Alison Lynch  
Alison Lynch, Pharmacist-in-Charge  
Wedgewood Village Pharmacy  
Respondent  
Dated: 3/31/16

Alan T. Rogalski  
Alan T. Rogalski (P4550)  
Attorney for Respondent  
Dated: 3/31/2016





**California State Board of Pharmacy**  
 1625 North Market Boulevard, Suite N219, Sacramento, CA 95834  
 Phone (916) 574-7900  
 Fax (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY  
 DEPARTMENT OF CONSUMER AFFAIRS  
 GOVERNOR EDMUND G. BROWN JR.

**February 27, 2018**

**CERTIFIED MAIL**

WEDGEWOOD VILLAGE PHARMACY LLC  
 ATTN: MARCY ANN BLISS, CEO  
 405 HERON DR SUITE 200  
 SWEDESBORO, NJ 08085

Tony J. Park  
 Attorney at Law  
 49 Discovery, Suite 240  
 Irvine, CA 92618

**RE: CI 2017 77042**

**WEDGEWOOD VILLAGE PHARMACY LLC  
 NRP 1826**

After thorough and careful consideration of the explanation and information you provided at the office conference, the committee determined that the information presented had been previously considered and was not new information. The committee decided to affirm the above-referenced Citation and Fine, CI 2017 77042 as originally issued.

This decision is the final administrative order regarding the Citation. Since you did not timely request a hearing to contest the Citation pursuant to California Code of Regulations, title 16, section 1775.4, subdivision (a), the administrative appeals process has concluded.

Failure to pay any imposed fine(s) within 30 days of the date of this letter may result in disciplinary action being taken. The timely payment of the imposed fine(s) shall not constitute an admission of the violation(s) charged in the Citation.

If any fine(s) are not timely paid, then the full amount of the unpaid fine(s) shall be added to the fee for the renewal of your license. Your license shall not then be renewed without full payment of the renewal fee and the assessed fine(s).

Please contact Associate Enforcement Analyst Jennifer Sevilla at (916) 574-7925, if you have any questions.

Sincerely

Virginia Herold  
 Executive Officer  
 Board of Pharmacy

**DECLARATION OF SERVICE BY CERTIFIED MAIL****RE: WEDGEWOOD VILLAGE PHARMACY LLC NRP 1826****Citation CI 2017 77042**

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 1625 North Market Boulevard, Suite N219, Sacramento, California 95834-1924.

On February 27, 2018, I served the attached:

Decision letter from office conference.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California, addresses as follows:

**NAME****CERTIFIED MAIL NO**

WEDGEWOOD VILLAGE PHARMACY LLC  
ATTN: MARCY ANN BLISS, CEO  
405 HERON DR SUITE 200  
SWEDESBORO, NJ 08085

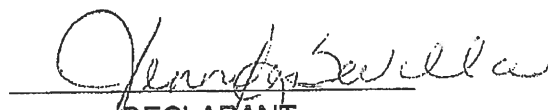
7017 0530 0001 1516 3558

Tony J. Park  
Attorney at Law  
49 Discovery, Suite 240  
Irvine, CA 92618

7017 0530 0001 1516 3565

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 27, 2018, at Sacramento, California.

  
\_\_\_\_\_  
DECLARANT  
Jennifer Sevilla  
Associate Enforcement Analyst

**BOARD OF PHARMACY  
DEPARTMENT OF CONSUMER AFFAIRS  
STATE OF CALIFORNIA**

**CITATION AND FINE**

<b>Citation Number</b>	<b>Name, License No</b>
CI 2017 77042	WEDGEWOOD VILLAGE PHARMACY LLC, NRP 1826

**JURISDICTION:** Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

<b>VIOLATION CODE SECTION</b>	<b>OFFENSE</b>	<b>AMT OF FINE</b>
Bus. & Prof. Code § 4059.5 subd. (b)	A dangerous drug or device transferred, sold or delivered within this state shall only be transferred, sold or delivered to a licensed entity of this board	\$1,000.00

**CONDUCT:**

Business and Professions Code section 4059.5, subdivision (b) a dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent. Wedgewood Village Pharmacy, located at 405 Heron Dr. Suite 200 Swedesboro, NJ 08085 was not in compliance with this section. Specifically, Wedgewood Village Pharmacy sold prescription items to S Gerson, who represented himself as Dr. M Burd in order to purchase those items. There was a policy in place to verify licenses, but, it did not catch the fraud. The discrepancy between Dr. Burd's address of record and the fraudulent address provided was not questioned.

**CITATION ISSUED ON:** October 13, 2017

**TOTAL AMOUNT OF FINE(S):** \$1,000.00

**PAYMENT OF FINE(S) DUE BY:** November 12, 2017

# NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane – Reno, NV 89509

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New Pharmacy or ☐ Ownership Change (Provide current license number if making changes: PH \_\_\_\_\_)  
Check box below for type of ownership and complete all required forms.  
☐ Publicly Traded Corporation – Pages 1,2,3,7      ☐ Partnership – Pages 1,2,5,7  
☒ Non Publicly Traded Corporation – Pages 1,2,4,7      ☐ Sole Owner – Pages 1,2,6,7

### GENERAL INFORMATION to be completed by all types of ownership

Pharmacy Name: Pharmaco Inc., dba Premier Infusion Care

Physical Address: 19500 Normandie Ave, Torrance, CA 90502

Mailing Address: 19500 Normandie Ave

City: Torrance State: CA Zip Code: 90502

Telephone: (866) 365-2525 Fax: (866) 383-2525

Toll Free Number: (866) 365-2525 (Required per NAC 639.708)

E-mail: contracting@premierinfusion.com Website: www.premierinfusion.com

Managing Pharmacist: John K. Rice, Rph, MBA License Number: 33317

### TYPE OF PHARMACY AND

### SERVICES PROVIDED

Yes/No

- ☐ ☒ Retail  
☐ ☒ Hospital (# beds \_\_\_\_\_)  
☐ ☒ Internet  
☐ ☒ Nuclear  
☐ ☒ Ambulatory Surgery Center  
☐ ☒ Community

☒ ☐ Other: Home infusion, specialty Pharmacy,

All boxes must be checked

For the application to be complete

Yes/No

- ☐ ☒ Off-site Cognitive Services  
☒ ☐ Parenteral \*\*  
☒ ☐ Parenteral (outpatient)  
☒ ☐ Outpatient/Discharge  
☒ ☐ Mail Service  
☐ ☒ Long Term Care  
☒ ☐ Sterile Compounding \*\*  
☒ ☐ Non Sterile Compounding  
☒ ☐ Mail Service Sterile Compounding \*\*  
☐ ☒ Other Services: \_\_\_\_\_

**\*\*If you check "yes" on any of these types of services, you will be required to make an appearance at the board meeting,**

101341



# APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, site fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized pharmacy may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable.

*John K. Rice, RPh*

Original Signature of Person Authorized to Submit Application, no copies or stamps

*John K. Rice, PPh, MBA*

Print Name of Authorized Person

*6/12/18*  
Date

Page 2

Board Use Only

Date Processed: \_\_\_\_\_

Amount: *\$500.00*

## APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

**OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**

State of Incorporation: California  
 Parent Company if any: Pharmaco, Inc  
 Mailing Address: 19500 Normandie Ave  
 City: Torrance State: CA Zip: 90502  
 Telephone: (806) 305-2525 Fax: (806) 383-2525  
 Contact Person: Sina Refua, Pharm D.

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a)	<u>Saman Refua</u>	<u>Alonzo Ave, Encino, CA 91316</u>
	Name	Address
b)	<u>John K. Rice, Rph, MBA</u>	<u>Granado Drive, Rancho Palos Verde, CA 90275</u>
	Name	Address
c)	<u>Sina Refua, Pharm D.</u>	<u>Century Park East #1912N, Los Angeles, CA 90067</u>
	Name	Address
d)	<u>_____</u>	<u>_____</u>
	Name	Address

- 2) Provide the number of shares issued by the corporation. 1209.5
- 3) What was the price paid per share? \$300,000 \$248.04 PER SHARE
- 4) What date did the corporation actually receive the cash assets? 2-2-2004
- 5) Provide a copy of the corporation's stock register evidencing the above information

See attachment

List any physician shareholders and percentage of ownership.

Name: \_\_\_\_\_ %: \_\_\_\_\_

Name: \_\_\_\_\_ %: \_\_\_\_\_

**Hours of Operation for the pharmacy:**

Monday thru Friday 8:30 am 7 pm      Saturday 9 am 5 pm

Sunday 10 am 6 pm      24 Hours on call

A Nevada business license is not required, however if the pharmacy has a Nevada business license please provide the number: N/A

**PHARMACO, INC.**  
**A CALIFORNIA CORPORATION DBA PREMIER INFUSION CARE**  
**AS OF JUNE 8, 2018**

**STOCK LEDGER**

Name of Shareholder	Place of Residence	From Whom	Certificates Issued		Certificates Surrendered		Consideration	Date of Transfer
			No.	No. of Shares	No.	No. of Shares		
All previous stock certificates Nos. 1-25 for Pharmaco, Inc. have been cancelled as of October 22, 2012 and share certificates re-issued to current shareholders as set forth below, representing 100% of the issued and outstanding shares of Pharmaco, Inc.								
Saman Refua	CA	Original Issuance (Replacement Certificate)	26	737.08	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
John K. and Deborah Lee Rice Family Trust Dated June 17, 2008	CA	Original Issuance (Replacement Certificate)	27	333.9	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
Sina Refua	CA	Original Issuance (Replacement Certificate)	28	138.52	—	—	\$248.04/share	Original issuance on 2/2/2004; replacement certificate No. 26 issued on 10/22/2012
Maria Lozzano	CA	Original Issuance (Replacement Certificate)	29	13	29	13	\$39,572 (\$3,044/share)	CANCELLED Original issuance on 10/22/2012; Certificate No. 29 cancelled on 2/1/2018 in connection with equity buy-out for all 13 shares

STATEMENT OF RESPONSIBILITY  
FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I, John K. Rice, RPh, MBA

Responsible Person of Pharmaco, Inc. dba Premier Infusion care

hereby acknowledge and understand that in addition to the corporation's, any owner(s), shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law that may occur in a pharmacy owned or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.

I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.

John K. Rice, RPh

Original Signature of Person Authorized to Submit Application, no copies or stamps

John K. Rice, RPh, MBA

Print Name of Authorized Person

6/18/18

Date



# AFFIDAVIT for Out-of-State Pharmacy License

STATE OF \_\_\_\_\_ )  
 ) ss.  
 \_\_\_\_\_ COUNTY )

I, John K. Rice, RPh, MBA, hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the PIC for Pharmaco, Inc., dba Premier Infusion Care (the Pharmacy), and in that capacity, I am authorized to speak on the Pharmacy's behalf.

2. I certify that upon licensure, the Pharmacy will not sell or ship compounded sterile products unto the state of Nevada, as indicated on the Pharmacy's application for a Nevada Out-of-State Pharmacy License.

3. I understand and acknowledge that the Pharmacy and any of its Nevada-registered/licensed staff members may be subject to discipline by the Board if the Pharmacy sells or ships any compounded sterile product into Nevada without first obtaining written authorization from the Board to do so.

4. I certify that if the Pharmacy ever decides to sell or ship any compounded sterile product into Nevada, the Pharmacy, through an authorized representative, will first notify the Board and obtain written approval to sell and ship such products into Nevada.

5. I understand that if the Pharmacy seeks approval to sell or ship compounded sterile product into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER AFFIANT SAYETH NOT.

I, John K. Rice, RPh, MBA, do hereby swear under penalty of perjury that the assertions of this affidavit are true.

John K. Rice  
 Name

SUBSCRIBED AND SWORN TO  
 before me, a notary public this  
 \_\_\_ day of \_\_\_, 20\_\_.

NOTARY PUBLIC

See attached



**CALIFORNIA JURAT WITH AFFIANT STATEMENT****GOVERNMENT CODE § 8202**

- ☒ See Attached Document (Notary to cross out lines 1-6 below)  
☐ See Statement Below (Lines 1-6 to be completed only by document signer[s], not Notary)

*(The following section is crossed out with a large X)*

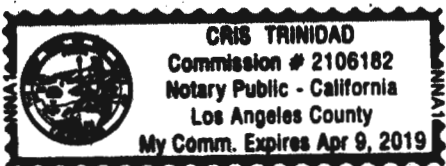
\_\_\_\_\_  
 Signature of Document Signer No. 1

\_\_\_\_\_  
 Signature of Document Signer No. 2 (if any)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California  
 County of Los Angeles

Subscribed and ~~sworn~~ to (or affirmed) before me  
 on this 12<sup>th</sup> day of June, 2018,  
 by John K. Rice  
 (1) \_\_\_\_\_



(and (2) \_\_\_\_\_),  
 Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence  
 to be the person(s) who appeared before me.

Signature *(Signature)*  
 Signature of Notary Public

Seal  
 Place Notary Seal Above

**OPTIONAL**

Though this section is optional, completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

**Description of Attached Document**

Title or Type of Document: Affidavit for out-of-state Pharmacy License Document Date: June 12, 2018  
 Number of Pages: 1 Signer(s) Other Than Named Above: No other Signers