OKLAHOMA

State Board of Pharmacy 2920 N LINCOLN BLVD STE A • OKLAHOMA CITY OK 73105-4200 pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov

Dr. Marty Hendrick, Pharm.D., D.Ph, Executive Director

Phone: 405.521.3815 • Fax: 405.900.8365

November 21, 2022

For facilities located outside of the United States (US).

If you have a presence in the United States you may access our website to make payment by MasterCard, Visa or EFT from a savings or checking account: <u>https://pay.apps.ok.gov/OSBP/payments</u>

If you do NOT have a US presence you will not be able to access our website.

Exception: If you are in Canada please contact me by phone at 405-522-3129 or <u>mterral@Pharmacy.ok.gov</u> for help to process payment on our online store from Canada.

If you need to pay by federal ACH wire transfer, please send me the email address of the person who will be making a federal ACH Wire transfer.

I will email them the information to make payment. Our Oklahoma State Treasurer (OST) requires that the payment information be sent to the person for the firm who will be making the payment for security reasons.

OST requires us to send the information split across two emails for security reasons.

If you have any questions or need assistance, please contact me.

If you haven't already, please mail / ship your completed application and documents

New applications to attention: Kristen Johnson

Renewal applications attention: Shakayla Gordon

OKLAHOMA STATE BOARD OF PHARMACY 2920 N LINCOLN BLVD STE A OKLAHOMA CITY OK 73105-4212

Returning to our permanent address effective 11/30/2022

Mary Ann Terral Principal Assistant, Direct 405-522-3129 OKLAHOMA STATE BOARD OF PHARMACY

	OKLAHOMA STATE BOARD OF PHAR 2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 7310 Phone: (405) 521-3815 / Fax: (405) 900-8365 www.pharmacy.ok.gov / e-mail: pharmacy@pharmacy		FOR OSBP USE ONLY ECEIPT: DATE:		
(No reside	2023-2024 NOTICE OF RENEWAL MANUFACTURER LICENSE y Name, DBA Name & Business Physical Address ntial address, include city/town, state/ ounty, ZIP & country):	Mailing Address:	DUE UPON RECEIPT (PAYMENTS MADE ONLINE ONLY) https://pay.apps.ok.gov/OSBP/payments/ Fee doubles 15 days after expiration EXPIRATION: LICENSE #:		
<u>Prescrij</u>	otion items sold in / shipped to Oklahoma: (√check all that apply)	Non-controlled (Rx) Controlled (CDS)	Compressed Medical Gas Devices API		
Designated Designated	ct Information [notice of any deficiencies will be sent to Facility Manager/Representative: Facility Manager Phone: one: Facility Fax:	E-Mail:			
C. Is this D. If YES,	facility a "virtual manufacturer"? Yes you must complete the following. Attach a sepanot process any applications for Manufacturers that use unlicensed Contract]No arate sheet if necessa	ary. If NO, skip to Section E.		
	Contract Manufacturers:	Wholesal	e Distributors/3PL Providers:		
Name:	OK Lic #:	Name:	OK Lic #:		
Name:	OK Lic #:	Name:	OK Lic #:		

E. Facility Registration / License Information.

Name:

1. FDA drug establishment or device establishment registration is required. (A COPY OF THE FACILITY'S FDA REGISTRATION MUST BE ATTACHED TO THIS APPLICATION)

2. If this facility is NOT LOCATED IN OKLAHOMA, the following must be submitted with this application:

a. Copy of Valid Home State License (Must provide copy of license, online verification printout will not be accepted)

Name:

- b. Copy of most recent inspection report (From home state, NABP, or FDA)
- c. Current Description of Operations

OK Lic #:

E. Ournershin	SOLE PROPRIETOR	CORPORATION	GOVERNMENT
F. Ownership	PARTNERSHIP	LLC	

Has there been any Change of Name, Ownership, or Location since your last application/renewal?

For Change/Notification Requirements, please refer to Oklahoma Pharmacy Rules, Section 535:25-3-7

Doe	s thi	s facilit	ty confe	orm to	US FDA	CGMP r	egulations	as required	by OAC	535:20-3·	-6.10?
		Yes	N	0	Virtual	Manufac	turer				

OK Lic #:

Does this facility have a written Drug Diversion Detection and Prevention Policy on file and availa required by OAC 535:20-3-4.1? Yes (REQUIRED)	ble for review as
Does this facility sell / ship directly to veterinarians located in Oklahoma? Yes No	

If "Yes" is your facility registered with the Oklahoma Veterinary Board?	Yes	
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G. Disciplinary History:

Please answer each of the following questions YES (Y) or NO (N). For the purpose of the questions below, "applicant" means the Manufacturer listed in Section A above. All "YES" answers MUST be explained in detail in a separate addendum.

The addendum shall identify the person/entity to whom the "Yes" answer applies and shall include the jurisdiction and all other information requested. Failure to disclose any of the requested information may result in the denial of this application and/or other appropriate action.

The addendum form that shall be used to provide this information may be found at: https://ok.gov/pharmacy/Licensees_&_Applicants/Forms_&_Applications/Facilities/index.html

1.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its designated representative or facility manager been convicted of any felony for conduct relating to manufacturing prescription drugs, any felony for violation of 21 U.S.C. § 331 (i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering?	Y or N
2.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its designated representative or facility manager pled guilty or nolo contendere to or been found guilty of violating federal or state requirements for licensure that present a threat of serious adverse health consequences or death to humans?	Y or N
3.	Since the last renewal or within the last 24 months, has the applicant or any of its owners or its designated representative or facility manager pled guilty or nolo contendere to or been found guilty of violating any federal or state felony offense statutes or any federal or state misdemeanor offense statutes involving prescription drugs and/or controlled substances? Are any such charges or indictments pending? (If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and all designated representatives or facility managers.)	Y or N
4.	Since the last renewal or within the last 24 months, has any federal (e.g., FDA, DEA) or state (e.g., OBNDD) regulatory or law enforcement agency found that the applicant or any of its owners or its designated representative or facility manager has violated any federal, state, or local laws or foreign laws? Is there any such action pending? (<i>If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and all designated representatives or facility managers.)</i>	Y or N
5.	Since the last renewal or within the last 24 months, has suspension, revocation or any other sanction been imposed against a license currently or previously held by the applicant or any of its owners or its designated representative or facility manager for violating federal or state laws? Since the last renewal or within the last 24 months, has the applicant or any of its owners or its designated representative or facility manager surrendered a license? (If the owner of the applicant is a business entity, these questions need not be answered as to partners, members, or stockholders of the owner unless such persons currently serve as managers, officers or directors of the owner or own more than twenty percent (20%) of the owner. These questions shall be answered as to the applicant and all designated representatives or facility managers.)	Y or N
6.	Since the last renewal or within the last 24 months, has the applicant had any application for a license or permit refused or denied by any licensing authority?	Y or N
7.	Since the last renewal or within the last 24 months, has the applicant had a registration issued by a controlled substance authority revoked, suspended, surrendered, limited or restricted?	Y or N

I swear and affirm under penalty of perjury pursuant to Title 21 O.S. 491 and/or discipline by the Board of Pharmacy under the pharmacy laws and rules of the State of Oklahoma that all information I have supplied herein is true and complete.

THIS SIGNATURE MUST BE NOTARIZED:

Printed Name of Facility Manager/Representative

Signature of Facility Manager/Representative

State of)	
County of)

No

Subscribed and sworn to or affirmed before me	

this _____ day of _____ , 20 ____ .

Notary Public

THE FOLLOWING MUST BE SUBMITTED WITH THIS APPLICATION:

- > \$200 Renewal Fee Receipt
- Copy of Home State License & Latest Inspection Report (Non-Resident)
- Current Description of Operations
- Copy of FDA Registration / Form 483 / Warning Notice (include response)
- Charges & Convictions Addendum (if applicable)

PLEASE MAKE SURE THIS APPLICATION IS COMPLETE AND ALL ATTACHMENTS ARE PRESENT BEFORE SUBMISSION. VERIFY SIGNATURES AND NOTARIES. ANY DEFICIENCIES COULD RESULT IN THIS APPLICATION BEING RETURNED. SHOULD THIS HAPPEN, YOU WILL BE SUBJECT TO ANY LATE FEES/RESINSTATEMENT FEES ASSESSED. ANY CERTIFICATE NOT RENEWED IS SUBJECT TO CANCELLATION 30 DAYS AFTER EXPIRATION.