



# OKLAHOMA STATE BOARD OF PHARMACY

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105  
Phone: (405) 521-3815 / Fax: (405) 521-3758  
www.pharmacy.ok.gov / e-mail: pharmacy@pharmacy.ok.gov

FOR OSBP USE ONLY	
RECEIPT:	
DATE:	

## 2021-2022 NOTICE OF RENEWAL MANUFACTURER LICENSE

**DUE UPON RECEIPT**

**(PAYMENTS MADE ONLINE ONLY)**  
<https://pay.apps.ok.gov/OSBP/payments/>  
**Fee doubles 15 days after expiration**

**EXPIRATION:** \_\_\_\_\_  
**LICENSE #:** \_\_\_\_\_

**A. Facility Name, DBA Name & Physical Address:**

**Mailing Address:**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Prescription items sold in / shipped to Oklahoma: (√check all that apply)	Non-controlled (Rx)	Compressed Medical Gas
		Controlled (CDS)

**B. Contact Information** [notice of any deficiencies will be sent to the email given below for the Facility Manager/Representative]:

Designated Facility Manager/Representative: \_\_\_\_\_

Designated Facility Manager Phone: \_\_\_\_\_ E-Mail: \_\_\_\_\_

Facility Phone: \_\_\_\_\_ Facility Fax: \_\_\_\_\_ Facility hours: Mon-Fri \_\_\_\_\_

**C. Is this facility a "virtual manufacturer"?** \_\_\_ Yes \_\_\_ No

**D. If YES, you must complete the following. Attach a separate sheet if necessary. If NO, skip to Section E.**

*\*OSBP will not process any applications for Manufacturers that use unlicensed Contract Manufacturers. This DOES include foreign manufacturers.*

Contract Manufacturers:		Wholesale Distributors/3PL Providers:	
Name:	OK Lic #:	Name:	OK Lic #:
Name:	OK Lic #:	Name:	OK Lic #:
Name:	OK Lic #:	Name:	OK Lic #:

**E. Facility Registration / License Information.**

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

F. Ownership	SOLE PROPRIETOR	CORPORATION	GOVERNMENT
	PARTNERSHIP	LLC	

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

\_\_\_ Yes \_\_\_ No *(If yes, a new application must be completed)*

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

**Does this facility conform to US FDA CGMP regulations as required by OAC 535:20-3-6.10?**

\_\_\_ Yes \_\_\_ No \_\_\_ Virtual Manufacturer

Does this facility have a written Drug Diversion Detection and Prevention Policy on file and available for review as required by OAC 535:20-3-4.1? \_\_\_ Yes **(REQUIRED)**

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 \_\_\_ No

**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](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? <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
4.	Since the last renewal or within the last 24 months, has any federal (e.g., FDA, DEA) or state (e.g., OBND) 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? <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
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 \_\_\_\_\_)

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.**