Oklahoma State Board of Pharmacy
2920 N. Lincoln Blvd., Ste. A OKC, OK 73105
Phone: (405)521-3815 - Fax: (405)900-8365
EM: Pharmacy@pharmacy.ok.gov
Marty Hendrick, Pharm. D, D.Ph., Executive Director

APPLICATION FOR OKLAHOMA FACILITY LICENSE

What you need to know before submitting an application- **PLEASE READ CAREFULLY**:

1. New applications (including change of owner, change of location, and change of name), if submitted without deficiencies, can take up to 2 weeks for processing.
2. The facility **SHALL NOT** operate from a place of residence.
3. Please verify all information requested on the application is provided at the time of submission to avoid any further delay.
4. Oklahoma requires up to 2 levels of ownership. Please pay special attention to Section D of the ownership form you are directed to on Page 1 of the application.
5. Oklahoma licenses are not transferable; they are only valid for the name and location that reflects on the license and the owner(s) reflected in the application submitted to obtain said license. This means that for change applications, the existing license will be ended at the time the new license is issued. ***For "Change of Owner" applications, as long as the previous/existing license has not expired, you may be able to continue contracts/orders as long as there is a Power of Attorney in place.*** <Please seek legal counsel for these types of situations>
6. For "New" or "Change of Location" applications- You cannot conduct business at the new facility until after you have been inspected and provided an Oklahoma license. Please be sure to plan ahead accordingly.
7. Please do not fax or email applications to the Board Office. We must have original signatures and notaries on file.
8. If there are any deficiencies with the application, our office will contact the designated facility manager/representative via email at the email address currently on file.
9. For Oklahoma facilities, once the application is processed it will be given to the proper Compliance Officer/Inspector, who will call the phone number listed on the application to schedule a time and date to perform the required inspection. **The facility must pass final inspection within ninety (90) days of application or the facility must resubmit the application and fees. Fees will not be refunded.** The license will be released on-site upon passage of this inspection.
10. OSBP Staff cannot interpret rules. For questions regarding what constitutes an ownership change, please refer to OAC 535:25-3-7.
11. OSBP reserves the right to request any additional information not specifically requested on this application deemed necessary to protect the public health and safety.

OKLAHOMA
State Board of Pharmacy

2920 N LINCOLN BLVD STE A • OKLAHOMA CITY OK 73105-4200
pharmacy@pharmacy.ok.gov • www.pharmacy.ok.gov
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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, American Express or EFT from a savings or checking account:

https://pay.apps.ok.gov/OSBP/payments

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 the Board by phone at 405-522-3815 or by email at pharmacy@pharmacy.ok.gov for help processing a payment on our online store from Canada.

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

The Board will email them the information to make payment. Our Oklahoma State Treasurer (OST) requires that the payment information be sent to the person who will be making the payment on behalf of the entity for security reasons.

OST requires us to send the information separately between 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: Shakayla Gordon
Renewal applications attention: Marquise Robertson

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

Information may be typed in before printing. Click the Reset button to clear the form.

OKLAHOMA STATE BOARD OF PHARMACY

2920 N Lincoln Blvd, Suite A, Oklahoma City, OK 73105
Phone: (405) 521-3815 / Fax: (405) 900-8365
Web Address: www.pharmacy.ok.gov
E-mail: pharmacy@pharmacy.ok.gov

Reset Form

FEE: $400 (ONLINE ONLY)
https://pay.apps.ok.gov/OSBP/payments/
(includes inspection and/or document review – physical inspection will occur for all in-state facilities)

MANUFACTURER LICENSE APPLICATION

√ Check all that apply		
	☐	NEW
	☐	CHANGE OF OWNERSHIP
	☐	CHANGE OF LOCATION
	☐	CHANGE OF NAME - Formerly Known As:

FOR OSBP USE ONLY:		
LICENSE	ISSUED	REPLACES
RECEIPT	DATE	

Prescription items sold in / shipped to Oklahoma: (√check all that apply)

☐	Non-controlled (Rx)	☐	Compressed Medical Gas
☐	Controlled (CDS)	☐	Devices

A. Facility Name, DBA Name & Business Physical Address: (Non-residential address, include city/town, state/province/county, ZIP & Country):

Mailing Address: (if different from Physical Address) (include city/town name, state/province/county, ZIP & Country):

B. Contact Information [notice of any deficiencies will be sent to the email given below for the *person responsible*]:

Person responsible for application:_____ E-Mail: _____

Designated Facility Manager/Representative: _____

Designated Facility Manager Phone:_____ E-Mail: _____

Facility Phone:_____ Facility Fax:_____ Facility hours: Mon-Fri _____

C. Ownership Information:

TYPE OF OWNERSHIP (√ one and attach the appropriate form to this application)						
	☐	SOLE PROPRIETOR *(complete Form A)*	☐	CORPORATION *(complete Form B1 or B2)*	☐	GOVERNMENT *(complete Form D)*
	☐	PARTNERSHIP *(complete Form A)*	☐	LLC *(complete Form C)*		

D. Is this facility a "virtual manufacturer"? ___Yes ___No **If YES, complete the following:**

1. **Contract Manufacturer(s)** ***(attach separate page if necessary)*****:**

Name Address FDA Reg #

Name Address FDA Reg #

2. **Wholesale Distributor(s) / 3PL Provider(s)** ***(attach separate page if necessary):***

Name Address OK Lic #

E. Does this facility conform to US FDA CGMP regulations as required by OAC 535:20-3-6.10?
____Yes ____No ____Virtual Manufacturer

F. 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)

G. Does this facility sell / ship directly to veterinarians located in Oklahoma?____Yes____No

H. If this Facility is LOCATED IN OKLAHOMA, complete the following:

1. This facility is located in _____ County of Oklahoma.

I. Facility Registration / License Information:

1. **FDA drug establishment or device establishment registration is required. Complete the following:** *(attach copy)*
   a. FDA Firm / Establishment Name:_____
   b. FDA Facility Establishment Identifier / Registration #: _____

c. FDA Expiration Date / Date of Registration Status: _____

d. FDA Drug Labeler Code: _____

2. **If this facility is NOT LOCATED IN OKLAHOMA, complete the following:** *(attach copy of license & inspection report)*

a. Home State:_____Type of License issued by Home State:_____

b. Home State license number:_____ Home State license expiration date:_____

c. Date of Last Inspection:_____ Entity conducting inspection:_____

J. 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 to Application with Charges & Convictions'* 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.	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?	
2.	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?	
3.	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 and facility managers.)*	
4.	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? *(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 and facility managers.)*	
5.	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? 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 and facility managers.)*	
6.	Has the applicant ever had any application for a license or permit refused or denied by any licensing authority?	
7.	Has the applicant ever had a registration issued by a controlled substance authority revoked, suspended, surrendered, limited or restricted?	

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:

1. ___ **$400 Application Fee Receipt**
2. ___ **Copy of FDA Registration**
3. ___ **Copy of Home State License(s)** ***(out-of-state facilities only)***
4. ___ **Copy of Last Inspection Report** ***(out-of-state facilities only)***
5. ___ **List of Contract Manufacturer(s) / Wholesale Distributor(s) / 3PL Provider(s)** ***(if applicable)***
6. ___ **Charges & Convictions Addendum** ***(if applicable)***
7. ___ **Ownership Form(s) with required attachment(s)** ***(see Section C)***

Physical inspection will occur for all in-state facilities. Board inspection must occur prior to opening for new in-state applicants. License expires annually – 12 months from issue.