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
Phone: (405) 521-3815 / Fax: (405) 521-3758
www.pharmacy.ok.gov / e-mail: pharmacy@pha

Reset Form

FEE: $400
(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 & Physical Address:

_____
_____
_____
_____
_____

Mailing Address: (if different from Physical Address)

_____
_____
_____
_____
_____

B. Contact Information:

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 *(attach separate page if necessary)*:**

Name Address FDA Reg #

Name Address FDA Reg #

2. **Wholesale Distributor / 3PL Provider *(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 ____ No

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 Registration (required):** *(attach copy)*
   a. FDA Firm / Establishment Name:_____
   b. FDA Facility Establishment Identifier / Registration #: _____

c. FDA Data Universal Numbering System #:_____

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

e. FDA Drug Labeler Code: _____

2. Home State License. If this facility is NOT LOCATED IN OKLAHOMA, complete the following: ***(attach copy)***

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**
2. ___ **Copy of FDA Establishment and/or Labeler Registration**
3. ___ **Copy of Home State License(s)** ***(if applicable)***
4. ___ **Charges & Convictions Addendum** ***(if applicable)***
5. ___ **Ownership Form(s) with required attachments** ***(see Section C)***

Applications are processed upon receipt. Please allow 2-3 weeks for processing of your license. Following processing, physical inspection will occur for all in-state facilities and may require an additional 1-2 weeks. Board inspection must occur prior to opening for new in-state applicants. License expires annually – 12 months from issue.