



FEE - \$200

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:	

Fee doubles 15 days after expiration
EXPIRES: _____

**2016-2017 NOTICE OF RENEWAL
MANUFACTURER LICENSE**

A. Facility Name, DBA Name & Physical Address: _____ **Mailing Address: (if different from Physical Address)** _____

License No. _____ Please PRINT clearly _____

Prescription items sold in / shipped to Oklahoma: (√check all that apply)	<input type="checkbox"/>	Non-controlled (Rx)	<input type="checkbox"/>	Compressed Medical Gas
	<input type="checkbox"/>	Controlled (CDS)	<input type="checkbox"/>	Devices

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. Is this facility a "virtual manufacturer"? Yes No **If YES, include the following:**

- Contract Manufacturer(s) - *Attach separate page including Name, Address & FDA Registration #*
- Third Party Logistics Provider(s) - *Attach separate page including Name, Address & OK 3PL License #*

D. Facility Registration / License Information:

- FDA Registration (required): (attach copy)**
 - FDA Firm / Establishment Name: _____
 - FDA Facility Establishment Identifier / Registration #: _____
 - FDA Data Universal Numbering Systems #: _____
 - FDA Expiration Date / Date of Registration Status: _____
 - FDA Drug Labeler Code: _____
- Home State License. If this facility is NOT LOCATED IN OKLAHOMA, complete the following: (attach copy)**
 - Home State: _____ Type of License issued by Home State: _____
 - Home State license number: _____ Home State license expiration date: _____
 - Date of Last Inspection: _____ Entity conducting inspection: _____

E. Ownership ^{1,2}	<input type="checkbox"/>	SOLE PROPRIETOR	<input type="checkbox"/>	CORPORATION	<input type="checkbox"/>	GOVERNMENT
	<input type="checkbox"/>	PARTNERSHIP	<input type="checkbox"/>	LLC	<input type="checkbox"/>	

List: [attach separate page if necessary]

• Name of Sole Proprietor Owner; or	1.
• Names of Partners, if Partnership; or	2.
• Name & Title of Corporate Officers (including President and Secretary), if Corp or LLC; or	3.
• Name of Government or Tribal Entity owning facility	4.

1. A change of ownership requires a new application. A change of ownership occurs when a change of ownership form occurs (e.g. from a sole proprietor to an LLC) or a change of 20% or more of the ownership of the entity owning the license occurs (for example, when the corporation owning the license sells 20% or more of the stock). For publicly traded corporations, a routine sale of stock is not a change of ownership. [see OAC 535:25-3-7(a)]

2. Changes in any information required for licensure must be reported to the Board within ten (10) days. [see OAC 535:25-3-7(b)]

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

___ Yes ___ No ___ Virtual Manufacturer

G. Does this facility have a written Drug Diversion Detection and Prevention Policy? ___ Yes ___ No *(required)*

H. Does this facility sell / ship directly to veterinarians located in Oklahoma? ___ Yes ___ No

I. 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:

<http://www.ok.gov/OSBP/documents/Charges%20%26%20Convictions%20Addendum.pdf>.

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 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 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:

1. ___ \$200 Renewal Fee
2. ___ List of Contract Manufacturer(s) & 3PL(s) *(if applicable)*
3. ___ Copy of FDA Registration
4. ___ Copy of Home State License(s) *(if applicable)*
5. ___ Charges & Convictions Addendum *(if applicable)*

If this facility has had a Name change, Ownership change or Address change you must complete a new application. Applications are available at www.pharmacy.ok.gov.

Please allow **3 weeks from date of receipt** for processing and mailing of your permit.
ANY CERTIFICATE NOT RENEWED IS SUBJECT TO CANCELLATION 30 DAYS AFTER EXPIRATION