APPLICATION FOR REGISTRATION
MANUFACTURER
IN AND OUT OF STATE
(Expires September 30 Annually)

APPLICATION REQUIREMENTS:

☐ **$525.00 application or owner/location change fee / $625.00 if distributing or handling controlled substances.**

☐ **Controlled substance application* & copy of active DEA registration.** ***If facility does not handle controlled substances, box indicating "Not Applicable" must be marked.

☐ **Responsible Party Attestation Form**

☐ **Copy of Resident State license/registration AND license/registration verification from Resident State** (required only for applicants located outside of Oregon). Online license/registration verifications accepted. Business name and owners listed on this application must match resident state verification.

☐ **If you answer "YES" to any disciplinary action questions,** including pending disciplinary actions, all notices, citations, etc. and fully executed Board orders must be provided along with a detailed explanation.

☐ **Signed Responsible Party Attestation Form**

***Priority processing will be given to complete applications.** All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will be expired. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.

Mail completed application and all required documentation to:	**Questions? Contact us:**
Oregon Board of Pharmacy 800 NE Oregon Street, Suite 150 Portland OR 97232	Telephone: (971) 673-0001 www.oregon.gov/pharmacy pharmacy.licensing@bop.oregon.gov

Please read the following instructions for applicants for registration as a Manufacturer.

1. Oregon Administrative Rule 855-060 defines and identifies Manufacturer registration requirements. https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3983

2. A registration will be issued once all required paperwork and fee(s) have been submitted and approved. This facility may not commence business in Oregon or permit products to be distributed into Oregon until the registration is issued.

3 A Manufacturer that distributes a product that they do not manufacture or does not hold either the NDA, ANDA or title to, from the location on this application, may also need to apply for registration as a Wholesaler in accordance with OAR 855-065-0006 or as Drug Distribution Agent in accordance with OAR 855-062-0001**.**

Note: A manufacturer registration permits the holder to distribute or arrange distribution of the drugs they manufacture directly from their registered manufacturing facility to a wholesaler or other distribution center one time without holding a separate registration as a wholesaler.

A manufacturer registration is required for a facility that is the first point of entry from a foreign manufacturer. If a drug or device is produced outside of the U.S. and its Territories, the first U.S. location

that receives the product is required to register as a manufacturer. The registration requirement does not include airports or ship ports.

4. Each company or location address, even if under common ownership, must submit a separate application for registration.

5. You must pay a registration fee for each application for **a New Registration, an Ownership Change or a Location Change**. The Board can only accept payment by check or money order. **All fees are nonrefundable.**

   Examples of a required ownership change application include but are not limited to: corporate restructure; LLC to a Corporation, Corporation to LLC; acquisition of assets; or additions or deletions of an owner. An ownership change requires submission of a copy of the sales agreement or other documentation that verifies proof of new ownership.

   If you are completing these forms to report a **Name Change** only, you do not pay a fee.

6. **Oregon Controlled Substance Registration**. The Controlled Substance Registration is required for all outlets that manufacture controlled substances. Be advised that the Controlled Substance Registration is not an independent registration. It must be issued in conjunction with a Manufacturer Registration.

   Applications will not be processed without the completion of the Controlled Substance Application. You must submit a copy of your DEA registration along with your application. If your facility **does not handle** controlled substances, please check the box "Not Applicable" and return it with the Application. Note: The controlled substance fee is **not** required if the application is marked "Not Applicable."

   Virtual Manufacturers must submit a copy of the contract manufacturer's or 3PL's DEA registration and fee.

7. **License/Registration Verification in Resident State** (required only for applicants located outside of Oregon) **Applications for out-of-state manufacturers will not be processed without this verification**.

   To prevent delays in processing, submit a completed verification form or letter from your resident state licensing agency **with your application(s)**. License verifications must be original and not tampered with, including the use of whiteout. Photocopies of registrations will not be accepted in lieu of a license verification from your resident state. If your license or registration can be verified online, a recent printout from the online system may be submitted along with a copy of the facility's resident license or registration.

   If your resident state does not issue you any type of professional or business license, attach an original letter dated within the last 24 months, from the state agency that licenses drug outlets, or a copy of the rules or regulations stating that you do not need a license/registration.

8. **Oregon Revised Statues and Administrative Rules** are accessible on our web site at: https://www.oregon.gov/pharmacy. You may purchase a set for $25 (check the box on the application if you wish to purchase one or more sets).

Please be aware that your registration will be issued upon approval once all required paperwork and fee(s) are processed. Your registration is to be in your possession *PRIOR* to conducting business in Oregon. Manufacturer Registrations expire September 30th, annually, and fees are not prorated.

APPLICATION FOR REGISTRATION

MANUFACTURER
In and Out of State
(Expires September 30 Annually)
Oregon Board of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232
Pharmacy.licensing@bop.oregon.gov

FOR BOARD USE ONLY	[0316] $525.00 [0310] $100.00 [0326] $ 25.00
RECEIPT #	
CHECK #	
ENTERED BY	
PERSON ID #	
APPLICANT ID #	

Please check all that apply:

- ☐ **Manufacturer Registration (with or without controlled substances)** **Fee: $525.00**
- ☐ **Controlled Substance Registration** **Fee: $100.00**
- ☐ **Laws & Rules per set, please indicate quantity_____** **Fee: $ 25.00**

TOTAL ENCLOSED:_____
ALL FEES ARE NONREFUNDABLE

Type of Application – Check all that apply:

☐ **New Facility Application - Start / Effective Date:** _____

☐ **Change of Ownership or Location Change – Effective Date of Change:** _____
A change of ownership or location **requires** the submission of a new application and registration fee **within 15 days**.

Registration Number: _____

☐ **Legal documentation of the change in ownership or control, for example, a stock purchase agreement and/or and executed contract for sale, etc.**

☐ **Registration Reinstatement (Registration has been lapsed for a period of one year or more)**

Registration Number: _____

☐ **Name Change Only (No fee required)**

Registration Number: _____

Please PRINT or TYPE

WARNING: ORS 689.405(1) The furnishing of false information is grounds to deny registration.

Trade or Business Name (DBA): _____

Full Legal / Owner Name: _____

Federal Tax ID # or Owner SSN: _____

Physical Location Address: _____

City: _____ State: _____ Zip: _____

Phone Number: _____ FAX # _____

Registration & Renewal Mailing Address: _____

City, State, Zip: _____

Licensing Contact Person: _____ Title _____ Contact Phone _____

Licensing Contact Person E-mail Address: _____

Facility Website: _____

Provide all of the following FDA registration numbers that apply to this location:

(a) New Drug Application number (NDA) _____

(b) Abbreviated New Drug Application number (ANDA) _____

(c) Labeler Code number (LC) or National Drug Code Number (NDC) _____

(d) FDA Central File Number (CFN) _____

(e) FDA Establishment Identifier number (FEI) _____

(f) Outsourcing Facility (503B) _____

Please answer all of the following – (only "Yes" or "No" answer is accepted)

1. 1. Has disciplinary action ever been taken, or is any such action currently pending or proposed against any of the persons or the facility listed on this application, by any State or Federal Authority in connection with a violation of any federal or state drug law or regulation? If "yes", attach a detailed explanation of the incident and describe any penalty incurred. You must provide a copy of all documents pertaining to discipline. This includes Notice of Disciplinary Actions, Board Orders and other related documents.	☐Yes ☐ No
2. Prior to shipping any product into or within Oregon, do you verify that the recipient is registered with the Oregon Board of Pharmacy? Note: All drug outlets, including contract manufacturers, wholesalers & 3PL's must register with the Oregon Board of Pharmacy	☐Yes ☐No
3. If you use a contract manufacturer, wholesaler or third party logistics provider to distribute your products, do you verify that the entity is registered with the Oregon Board of Pharmacy?	☐Yes ☐No
4. Do you physically manufacture product(s) at the physical location listed on page 1 of this application for registration? *If "no", identify below who manufactures your products(s) under contract. List Contract Manufacturer(s) names & physical addresses (if there is insufficient space on this form, you may attach additional sheets).	☐Yes ☐No*****
5. List the types of products that you manufacture below. You must provide the products manufactured, even if you do not physically manufacture at the location listed on page 1 of this application. Note: All drug outlets, including contract manufacturers, wholesalers & 3PL's must register with the Oregon Board of Pharmacy.	
6. Do you hold the title, NDA or ANDA for all these products? If "no: please list the Title, NDA or ANDA holder and explain your relationship to the holder.	☐Yes ☐No

7. Do you possess any drugs and/or devices at the physical location listed on page 1 of this application?	☐Yes ☐No
8. Does the name and address of this location appear on the label of the product(s) that are being manufactured? *If "no", please explain.	☐Yes ☐No*
If you answered "no" to all questions #6-8, you may need to register as a Drug Distribution Agent under OAR 855-062-003 instead of a Manufacturer.	
9. Do you physically distribute any drugs that you do not manufacture or for which you do not hold title, NDA or ANDA, or which do not have your name on the label? (*If "yes", you need to apply for a Wholesaler or Drug Distribution Agent registration **in addition to** this registration.) List Products:	☐Yes* ☐No
10. This facility manufactures or distributes controlled substances. If "yes", you must complete pages 5 and 6 of this application. *Oregon Schedules of Controlled Substances may be found at:* https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=3987 *and may be different from the Federal schedules. You must comply with the most stringent.*	☐Yes ☐No
10a. This facility is a virtual manufacturer with controlled substances and has verified that the distributor has obtained the required DEA Controlled Substance registration. (*If yes, you must attach a copy of the distributor's DEA registration with this application)	☐Yes* ☐No
11. Is this facility a small business? A small business is defined as a corporation, partnership, sole proprietorship or legal entity, which is independently owned and operated from all other businesses and which has 50 or fewer employees?	☐Yes ☐No

Product Distributor(s):
Please list the primary distributors you use, including your exclusive distributors, third–party logistics providers and wholesalers. If there is insufficient space on this form, you may attach additional sheets.

Name: _____ Distributor's Oregon Registration Number: _____

Physical Address: _____

City, State Zip: _____

Name: _____ Distributor's Oregon Registration Number: _____

Physical Address: _____

City, State Zip: _____

Name: _____ Distributor's Oregon Registration Number: _____

Physical Address: _____

City, State Zip: _____

Ownership Information

Type of Ownership:

☐ Publicly Held Corporation ☐ Corporation ☐ Limited Liability Company ☐ Sole Proprietorship

☐ Partnership – Including Limited Liability Partnership and Limited Partnership ☐ Charitable Organization

☐ Government / Educational Institution

Owner Name _____

Parent Company Name (If owned by another entity) _____

Complete the information below for all owners. You must include at least one of the following: CEO, President, Owner, or Members of LLC and Registered Agent. If a corporation, include the names of the corporate officers and the names of the stockholders who own the five largest interests.

1. Name _____

Title _____

SSN/Federal Tax ID _____

Address _____

City, State, Zip _____

Phone Number _____

Email Address _____

2. Name _____

Title _____

SSN/Federal Tax ID _____

Address _____

City, State, Zip _____

Phone Number _____

Email Address _____

3. Name _____

Title _____

SSN/Federal Tax ID _____

Address _____

City, State, Zip _____

Phone Number _____

Email Address _____

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Attestation Form

Part 1 – Responsible Party Information - To be completed by an authorized individual of the applicant. This must be an individual who may legally sign on behalf of the business and is responsible for compliance with Oregon Laws and Rules.

First Name :_____ Last Name:_____

Title_____

Facility Name:_____

Facility Address:_____

Facility City, State, Zip:_____

Part 2 – Attestation - To be completed by the responsible party listed above (person who may legally sign for the business). *Must be manually signed in ink.*

Per Oregon Revised Statue 689.401(1) The furnishing of false information is grounds to deny registration.

I swear or affirm that all information, statements, answers, and representations made in this application and the documents attached are true and correct, that the individuals at this facility are familiar with the laws and rules of the Oregon Board of Pharmacy as well as applicable federal laws, and that the business will be operated in compliance with all applicable laws and regulations.

I certify that if disclosed disciplinary action has been taken or is currently pending or proposed, the required documentation is attached to this application. I understand that failure to provide the required documentation may be grounds for denial of my application or disciplinary action against this facility.

Signature:_____ Date:_____

Printed Name:_____

CONTROLLED SUBSTANCE APPLICATION
APPLICATION FOR REGISTRATION UNDER
OREGON CONTROLLED SUBSTANCE ACT

OREGON BOARD OF PHARMACY
800 NE OREGON STREET, SUITE 150
PORTLAND OR 97232
pharmacy.licensing@bop.oregon.gov

FOR BOARD USE ONLY [0310] $ 100.00

RECEIPT # _____

CHECK # _____

PERSON ID # _____

CONTROLLED SUBSTANCE APPLICATION FEE $100.00 ***ALL FEES ARE NONREFUNDABLE***

Type of Application – Check all that apply:

☐ **Not Applicable. This facility does not handle or distribute Controlled Substances.**

☐ **This is a new registration.**

☐ **This is a change in owner or location.**

☐ **I wish to add a Controlled Substance registration to my existing facility.**

Oregon Registration Number: _____

☐ **I wish to reinstate a Controlled Substance registration to my existing facility.**

Oregon Registration number: _____

Please PRINT or TYPE

WARNING: ORS 475.135(1)(e) The furnishing of false information is grounds to deny registration.

Trade or Business Name (DBA): _____

Full Legal / Owner Name: _____

Federal Tax ID # or Owner SSN: _____

Physical Location Address: _____

City: _____ State: _____ Zip: _____

Phone Number: _____ FAX # _____

Registration & Renewal Mailing Address: _____

City, State, Zip: _____

Licensing Contact Person: _____ Title _____ Contact Phone _____

Licensing Contact Person E-mail Address: _____

DRUG SCHEDULES (Check appropriate box(es):

☐ Schedule I ☐ Schedule II ☐ Schedule II N ☐ Schedule III ☐ Schedule III N ☐ Schedule IV ☐ Schedule V

Attach a list of stocked Schedule I Drugs: [ ] Narcotic [ ] Non-Narcotic

ALL APPLICANTS MUST ANSWER THE FOLLOWING:

1. Are you currently registered to manufacture, distribute or otherwise handle the controlled substances in the schedules for which you are applying under the laws of the Federal Government?	☐Yes ☐ No
2. Have any of the persons or establishments listed on this application been convicted of a felony in connection with controlled substances under state or federal law?	☐Yes ☐No
3. If the applicant is a corporation, association, or partnership, has any officer, partner or stockholder been convicted of a felony in connection with controlled substances under state or federal law?	☐Yes ☐No
4. Have any of the persons or establishments listed on this application ever surrendered a previous Federal Controlled Substances Registration (FCSA) or had a FCSA Registration revoked, suspended or denied?	☐Yes ☐No
5. If the applicant is a corporation, association or partnership, has any officer, partner, or stockholder surrendered a FCSA Registration or had a FCSA Registration revoked, suspended or denied?	☐Yes ☐No
IF THE ANSWER IS YES TO ANY OF QUESTIONS 2 THROUGH 5, YOU MUST ATTACH A LETTER SETTING FORTH THE CIRCUMSTANCES.	
CURRENT FEDERAL REGISTRATION NUMBER _____ (You must submit a copy of your DEA registration along with this application.)	

Print or Type Name of Authorized Individual _____ Signature of Authorized Individual _____ Date _____

ALL RETURNED CHECKS WILL BE ASSESSED A $35.00 RETURNED PAYMENT FEE PURSUANT TO ORS 30.701(5)

FINAL CHECKLIST:	
1.	Appropriate Fee Included?
	☐ $525.00 new application or owner/location change fee ☐ $100.00 new Controlled Substance application or owner/location change fee (If required) **NOTE: Fees are not prorated.** Any registration issued prior to **September 30** will require renewal and payment of the renewal fee. Renewal information will be provided with the newly issued registration. All renewals submitted on October 1st or later are subject to a late fee of $100.00. **Total Fee Enclosed:** _____
2.	Required Documentation* – an application is incomplete if all requested documentation is not provided. *Priority processing will be given to complete applications. All applications submitted to the Board that are not complete and processed within 6 months from applicant signature will expire. Once expired, applicants who wish to continue with the application process must reapply by submitting a new application, along with all documentation, and all fees.
A.	☐ Copy of Resident State license/registration **AND** license/registration verification from Resident State (required only for applicants located outside of Oregon). Online license/registration verifications accepted. Business name and owners listed on this application must match resident state verification.
B.	☐ If you answer "YES" to any disciplinary questions, disciplinary actions, pending disciplinary actions and fully executed Board orders must be provided along with a detailed explanation**.**
C.	☐ Signed Responsible Party Attestation
D.	☐ Controlled substance application & copy of active DEA registration, if applicable. Please be sure to check the correct box on page 5.
E.	☐ All signatures

The undersigned hereby states that all the information contained in this application for registration is complete, true and correct; that they have read and are familiar with the applicable laws and rules of the Oregon Board of Pharmacy; and that such provisions of the law will be faithfully observed.

_____	_____	_____
Signature	Title (Owner, Partner, Etc.)	Date

ALL RETURNED PAYMENTS WILL BE ASSESSED A $35.00 RETURNED PAYMENT FEE PURSUANT TO ORS 30.701(5)

LICENSE VERIFICATION REQUEST FORM

OREGON BOARD OF PHARMACY
800 NE OREGON STREET, SUITE 150
PORTLAND OR 97232
TELEPHONE: (971) 673-0001
www.oregon.gov/pharmacy

Out-of-State Establishments Only

Verification Form of License/Registration in Resident State (required for all facilities located outside the State of Oregon). Applications for out-of-state facilities will not be processed without this verification.

To prevent delays in processing, submit a completed verification form or letter from your resident state licensing agency with your application(s). License verifications must be original and not tampered with, this includes the use of whiteout. Photocopies of registrations will not be accepted in lieu of a license verification from your resident state. If your license or registration can be verified online, a recent printout from the online system may be submitted along with a copy of your license or registration. If your resident state does not issue you any type of professional or business license, attach an original letter from the state agency that licenses drug outlets stating that you do not need a license.

To be completed by Applicant. You are responsible for sending this document to your resident State licensing agency for their verification and state seal. You must also attach a photocopy of your registration or license.

Resident State License Number _____

License Type _____

Business Name _____

Physical Address _____

City, State, Zip Code _____

To be completed by Resident State licensing/regulatory board or agency and returned to the applicant:

The outlet listed above has applied for a Manufacturer registration with the Oregon Board of Pharmacy. This registration is required of any manufacturer located within or out of this state that is engaged in the distribution of drugs within Oregon.

Written verification that this establishment has a current license or registration and is in good standing with its resident state is required for our licensing process. Please complete the section below and return it to the applicant.

[ ] The outlet listed above holds a current, unrestricted license or registration with our agency and has no disciplinary action pending.

[ ] Other (please explain): _____

_____

_____
Print Name & Title

_____
Authorized Signature

_____
Date

(*State Seal Required*)