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
Telephone: (971) 673-0001
www.pharmacy.state.or.us

Manufacturer Registration
Fee: $400.00
Controlled Substance Registration (If Applicable)
Fee: $50.00
Laws & Rules (If Needed)
Fee: $25.00
ALL FEES ARE NON REFUNDABLE

Dear Applicant:

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

1. Oregon Administrative Rule 855-060-0004 lists those persons who are required to register as a Manufacturer. http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_060.html

2. We will process your registration when we have received all required paperwork and fee(s). You may not commence business in Oregon or permit products you manufacture to be distributed into Oregon until your 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 855-065-0001.

Note: A manufacturer registration permits the holder to distribute the drugs they manufacture directly from the 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 be registered. 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.

Examples of a required ownership change application include: 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. We can only accept payment by check or money order. All fees are non refundable.

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.”

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, 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 home 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.

8. **Oregon Revised Statues and Administrative Rules** are accessible on our web site at: [http://www.pharmacy.state.or.us](http://www.pharmacy.state.or.us). You may purchase a hard copy or CD 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 license is to be in your possession PRIOR to doing business in Oregon. Manufacturer Registrations expire September 30th, annually, and fees are not prorated. **Renewals are due and must be post-marked by August 31st**, annually, which is one (1) month prior to the expiration date of your license. Renewal notices are generally mailed out mid-July.
APPLICATION FOR REGISTRATION

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(Expires September 30 Annually)
Oregon Board Of Pharmacy
800 NE Oregon Street, Suite 150
Portland OR 97232
Telephone: (971) 673-0001
www.pharmacy.state.or.us

Please check all that apply:
[  ] Manufacturer Registration (with or without controlled substances)  Fee: $400.00
[  ] Controlled Substance Registration  Fee: $ 50.00
[  ] Laws & Rules per set, please indicate quantity______  Fee: $ 25.00

PLEASE CHECK APPROPRIATE BOXES:
[  ] New Outlet  Start / Effective Date: ______________________
[  ] License Reinstatement [  ] Owner Change [  ] Location Change [  ] Name Change Only - No fee required
   License Number: __________________ Date Effective: ______________________

A change of ownership or location requires the submission of a new application and registration fee within 15 days.

Please PRINT or TYPE

Business Name (DBA): ____________________________________________
Corporate / LLC Name: __________________________________________
Federal Tax ID # or Owner SSN: ___________________________________
Location Address: ________________________________________________
City, State, Zip: ________________________________________________
Phone Number: (___) - _______ FAX # (___) - _______
License & Renewal Mailing Address: ________________________________
City, State, Zip: ________________________________________________
Licensing Contact Person: ___________________ Title _______ Contact Phone _______
Licensing Contact Person E-mail Address: ___________________________

Please 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:

1. [ ] Yes [ ] No Has disciplinary action ever been taken, or is any such action currently pending 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.
2. [ ] Yes [ ] No  Prior to shipping any product into or within Oregon, do you verify that the recipient is registered with the Oregon Board of Pharmacy?

3. [ ] Yes [ ] No  Do you physically manufacture product(s) at the location listed on page 1 of this application for registration?

List the types of product(s) that you manufacture:
(Please provide products manufactured, even if you do not physically manufacture products at the location listed on page 1 of this application.)

If the answer to question 3 above is "no", identify below who manufactures your product(s) under contract.

Contract Manufacturer(s): (Name(s) & Address(es))

Note: All drug outlets, including contract manufacturers, must register with the Oregon Board of Pharmacy. If there is insufficient space on this form, you may attach additional sheets.

4. [ ] Yes [ ] No  Do you hold the title, NDA or ANDA for all these products?

If "no", please explain your relationship with the holder.

Title, NDA or ANDA holder:

5. [ ] Yes [ ] No  Do you possess any drugs at this location?

6. [ ] Yes [ ] No  Does the name and address of this location appear on the label of the product(s) that are being manufactured?

If no, please explain:

* If you answered “no” to all questions #3-6, you may need to register as a Drug Distribution Agent under OAR 855-062-0003 instead of a Manufacturer.

7. [ ] Yes [ ] No  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?

Products:

* If “yes” to question 7, you need to apply for a Wholesaler Registration or Drug Distribution Agent in addition to this registration.

8. Please list the primary distributors you use, including your exclusive distributors, third–party logistics providers and wholesalers.

Distributors’ name(s) and address(es):

If there is insufficient space on this form, you may attach additional sheets.

CONTROLLED SUBSTANCE INFORMATION:  If NOT applicable, please check here: [ ]

If you manufacture controlled substances, please complete the next 5 questions.

Oregon Schedules of Controlled Substances may be found at:
http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_855/855_080.html and may be different from the Federal schedules. You must comply with the most stringent.

DRUG SCHEDULES (Check all that apply)

[ ] Schedule I  [ ] Schedule II  [ ] Schedule III  [ ] Schedule III  [ ] Schedule IV  [ ] Schedule V

1. Is the facility listed on this application 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

DEA REGISTRATION NUMBER ________________________________
2. If you are a corporation, association or partnership, has any officer, partner or stockholder ever been convicted of a felony in connection with controlled substances under state or federal law? [ ] YES [ ] NO

3. Has the applicant ever surrendered a previous Federal Controlled Substances Registration (FCSA) or had a FCSA Registration revoked, suspended or denied? [ ] YES [ ] NO

4. If the applicant is a corporation, association or partnership, has any officer, partner, or stockholder ever 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 4, attach letter of explanation.

Please select all that apply:

[ ] I wish to have this registration issued once a complete application and payment is received. Because the Oregon Board of Pharmacy does not prorate fees, I realize that by having my registration become effective before the beginning of the renewal period (October 1) my license will not be valid for a full year.

[ ] I wish to have this registration become effective on the next October 1st. (only applicable for new outlets)

The undersigned hereby states that all the information contained in this application for registration is 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 ___________________________

MAIL THIS APPLICATION WITH REQUIRED DOCUMENTS, AND FEES, PAYABLE TO THE OREGON BOARD OF PHARMACY
ALL RETURNED CHECKS WILL BE ASSESSED A $35.00 RETURNED CHECK FEE PURSUANT TO ORS 30.701(5)
Ownership Information

Publicly Held Corporation [ ] Yes [ ] No

If No, 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 the LLC and Registered Agent.

1. Name and Title  ________________________________________________
   SSN/Federal Tax ID  ________________________________________________
   Address  ________________________________________________
   City, State, Zip  ________________________________________________
   Phone Number  ________________________________________________
   Email Address  ________________________________________________

2. Name and Title  ________________________________________________
   SSN/Federal Tax ID  ________________________________________________
   Address  ________________________________________________
   City, State, Zip  ________________________________________________
   Phone Number  ________________________________________________
   Email Address  ________________________________________________

3. Name and Title  ________________________________________________
   SSN/Federal Tax ID  ________________________________________________
   Address  ________________________________________________
   City, State, Zip  ________________________________________________
   Phone Number  ________________________________________________
   Email Address  ________________________________________________

This page may be duplicated as needed
Out-of-State Establishments Only

Verification Form of License/Registration in Resident State (required for all Drug Distribution Agents, Manufacturers and Wholesalers located outside the State 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, 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 home 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 licensing/regulatory 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)
OREGON PHARMACY LAWS AND ADMINISTRATIVE RULES

Please Mail to:

NAME __________________________________________

FACILITY NAME _______________________________________

ADDRESS __________________________________________

CITY, STATE & ZIP CODE _______________________________________

Number of sets requested ________________ Amount enclosed $______________ ($25.00 per set)

Set(s) ordered for:

Pharmacist [ ] Intern [ ] Pharmacy [ ] Other [ ]

Make checks payable to: Oregon Board of Pharmacy
800 NE Oregon St, Ste 150
Portland, OR 97232

Please Note:

• Administrative Rules are updated through the Secretary of State’s Office within 30 days of being filed.

• Electronic versions of pharmaceutical references listed under Oregon Administrative Rule 855-041-1035 satisfy the minimum equipment requirement for a pharmacy.

• Sign up to receive the Oregon Board of Pharmacy Newsletters, Meeting Agendas and Rulemaking Notices - http://www.oregon.gov/pharmacy/Pages/Newsletters.aspx

• A PDF version of the Laws and Rules for the Oregon Board of Pharmacy may be found on the Boards website at http://www.oregon.gov/pharmacy/Pages/Laws_Rules.aspx

• Included are:
  o Oregon Revised Statute Chapter 689, Oregon Pharmacy Act
  o Oregon Revised Statute Chapter 475, Uniform Controlled Substance Act
  o Oregon Administrative Rules Chapter 855

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