

**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: \$15.00

ALL FEES ARE NON REFUNDABLE

Dear Applicant:

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

1. Oregon Administrative Rule 855-060-0003 lists those persons who are required to register as a Manufacturer. <http://www.oregon.gov/Pharmacy/Imports/Rules/June09/855-060.pdf>
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 we have notified you that we have approved the application. Registrations expire September 30 each year. We do not prorate fees. We will mail out renewal notices in mid-July and you must return renewal applications with the fee, post-marked by August 31.
3. **A Manufacturer that distributes a product that they do not manufacture or do not hold either the NDA, ANDA or title to, from the location on this application must also apply for registration as a Wholesaler in accordance with OAR 855-065-0006.** If you do not at any time take ownership or possession of any drug, and your name is not on the label, you may need to register as a Drug Distribution Agent (see separate application). 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.
4. Each company, 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**. 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. It is not a stand-alone registration. If you do not manufacture controlled substances, please check the box "Not Applicable". The controlled substance fee is **not** required if the application is marked "Not Applicable."
7. **Oregon Revised Statutes and Administrative Rules** are accessible on our web site at: <http://www.pharmacy.state.or.us>. You may purchase a hard copy or CD for \$15 (check the box on the application if you wish to purchase one or more sets).
8. **Ownership:** Please complete and submit the **Ownership** form for our records.
9. **License/Registration Verification in Resident State** (required only for applicants located outside of Oregon) We cannot process your application without this verification. To prevent any delay in processing, submit a completed verification form or original letter from your home state licensing agency with your application. 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.

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FOR BOARD USE ONLY	[0316] \$400.00
	[0310] \$ 50.00
	[0326] \$ 15.00
RECEIPT #	_____
BATCH DATE-NUMBER	_____
ENTERED BY	_____

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: \$ 15.00**

TOTAL ENCLOSED: _____
ALL FEES ARE NON REFUNDABLE

- New Outlet Start Date _____
- Owner Change Date Effective _____ Current Registration Number _____
- Location Change Date Effective _____ Current Registration Number _____
- Name Change Only Date Effective _____ Current Registration Number _____

You must submit a new application and registration fee within 15 days of a change of ownership or location.

Please PRINT or TYPE **WARNING:** ORS 475.135(1) (e) and ORS 689-405(1) The furnishing of false information is grounds to deny registration.

Business Name _____

Location Address _____

Phone Number () - FAX # () -

City, State, Zip _____

Mailing Address _____

City, State, Zip _____

Contact Person _____ Title _____ Contact Phone _____

Federal Tax ID # _____ Email Address: _____

You must provide at least one of the following FDA registration numbers:

- (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) _____

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 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.

2. Yes No Before distributing a drug, do you verify that the recipient is legally authorized to receive the drug?

3. Yes No Do you physically manufacture product(s) at the location listed on page 1 of this application for registration? If "yes", list the product(s) that you manufacture.

Product(s) Manufactured: _____

If "no", identify below who manufactures your product(s) under contract. If there is insufficient space on this form, you may attach additional sheets.

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 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", you need to apply for a Wholesaler Registration 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/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. Are you currently registered by the DEA to manufacture, distribute or otherwise handle controlled substances in the schedules for which you are applying under the laws of the Federal Government? YES NO

DEA REGISTRATION NUMBER _____

2. Have you ever been convicted of a felony in connection with controlled substances under state or federal law? [] YES [] NO
3. 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
4. Have you ever surrendered a previous Federal Controlled Substances Registration (FCSA) or had a FCSA Registration revoked, suspended or denied? [] YES [] NO
5. If you are 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 5, attach letter of explanation.

Please select all that apply:

- [] I wish to have my registration application processed on the date you receive my complete application and payment in your office. 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 my registration become effective on the next October 1st. (only applicable for new outlets)
- [] Enclosed is \$15 for a [] CD or [] a paper copy (check one) of the Oregon Board of Pharmacy's laws and rules. If you need more than one copy, indicate how many and enclose \$15 per copy.)

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

Print or Type Name of Applicant

Signature of Applicant or Authorized Individual

Date

MAIL THIS APPLICATION WITH REQUIRED DOCUMENTS, AND FEES, PAYABLE TO THE
OREGON BOARD OF PHARMACY

ALL RETURNED CHECKS WILL BE ASSESSED A \$25.00 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 this form for all owners. If publicly held corporation, list CEO or President and Registered Agent.
This page may be duplicated as needed.

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 _____

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License/Registration Verification in Resident State

License/Registration Verification in Resident State (required for all Drug Distribution Agents, Manufacturers and Wholesalers located outside the State of Oregon). To prevent any delay in processing, submit this form or an original letter from your home state licensing agency with your application. 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. You must 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 above person has applied for a Drug Distribution Agent, Manufacturer or Wholesaler Registration with the Oregon Board of Pharmacy. This registration is required of any resident or non-resident drug outlet that is engaged in the distribution of drugs within Oregon.

Written verification that this person 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