

Pharmaceutical Manufacturer License Application Packet

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In order to process your request:

Mail your application with initial documentation and your check or money order payable to:

Department of Health PO Box 1099 Olympia, WA 98507-1099

Send other documents not sent with initial application to:

Pharmacy Quality Assurance Commission Credentialing PO Box 47877 Olympia, WA 98504-7877

Contact us:

360-236-4700

To request this document in another format, call 1-800-525-0127. Deaf or hard of hearing customers, please call 711 (Washington Relay) or email <u>civil.rights@doh.wa.gov</u>

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Application Instructions Checklist

When your application for pharmaceutical manufacturer license is received by the Department of Health, you will be notified of any outstanding documentation needed to complete the process.

Note: If you are applying for a Control Substance Act registration in addition to your manufacturer license, be sure to send the additional nonrefundable fee.

All non-resident and out-of-state applicants must provide a copy of the resident license and last inspection.

Indicate type of application—new, change of ownership, change of location, or name change.

- **New**—First time requesting a manufacturer license.
- **Change of Ownership**—When name of legal owner/operator changes resulting from the sale of licensed agency.
- **Change of Location**—Changing the location address of manufacturer. Be sure to include you current license number.
- **Name change only**—Changing the name of your manufacturer. Be sure to list your current facility name.

Check One:

Please check your legal owner/operator business structure type according to your Washington State Master Business License.

Application Fee: you can check the <u>fee page</u> for current fees.

1. Demographic Information:

Uniform Business Identifier Number (UBI #): Enter your Washington State UBI #. All Washington State businesses must have UBI #s. City, county, and state government documents also have UBI #'s.

Federal ID Number (FEIN #): Enter your Federal ID Number, if the business has been issued one.

Legal Owner/Operator Name: Enter the owner's name as it appears on the UBI/ Master Business License.

Mailing Address: Enter the owner's complete mailing address.

Phone and Fax Numbers: Enter the owner's phone and fax numbers.

Email and Web Address: Enter your email address, if you have one.

Facility/Agency Name: Enter the agency's name as advertised on signs, brochures or Web site.

Physical Address: Enter	the agency's physical	street location	including c	ity, state,
zip code, and county.				

Phone and Fax Numbers: Enter the agency's phone and fax number.

Mailing Address: Enter the agency's mailing address, if different than physical address.

2. Facility Specific Information:

Type of Manufacturer: Check all types of manufacturers that apply.

Drug Enforcement Administration (DEA) Number: Enter your DEA Registration Number.

Background Questions: Check yes or no and if you check yes, list and explain on a separate sheet of paper.

3. Contact Information:

Enter name, title, phone number, fax number, and email address.



4. Additional Information:

Corporation Information: Enter date of incorporation, corporate number, and state of corporation.

Legal Owner: List the names, titles, addresses, and phone numbers of the corporate officers, partners, members, managers, etc. Attach an additional sheet of paper as needed.

Change of Ownership Information: List the previous legal owner name, previous name of facility, previous license number, effective date of ownership change and physical address, if applicable.

Signature:

Signature of legal owner or authorized representative.

Date signed.

Print name of legal owner or authorized representative.

Print title of legal owner or authorized representative.

Signature of responsible person for facility.

Date signed.

Print name of responsible person for facility.

Print title of responsible person for facility.





Revenue 0262010000

Pharmaceutical Manufacturer License Application					
This is for:					
☐ New ☐ Change of Ownership ☐ Ch	ange of Locati	on—Current License	#		
	-				
☐ Name Change Only—Current Facility Na	ime				
Check One					
Association	nited Partnersh	ip 🔄 Sole Pro	oprietor		
Corporation Mu	nicipality (City)	State Government Agency			
🗌 Federal Government Agency 🔄 Mu	nicipality (Cour	nty) 🛛 🗌 Tribal G			
	n-Profit Corpor	• /	0.1		
	tnership				
1. Demographic Information	•				
UBI#		Federal Tax ID (FEII	N) #		
021 //			() //		
Legal Owner/Operator Name					
Legal Owner/Operator Name					
Mailing Address					
City	State	Zip	County		
Phone (enter 10 digit #)		Fax (enter 10 digit #)			
Email Address		Web Address:			
Facility/Agency Name (Business name as a	dvertised on si	igns or Web site)			
Physical Address					
City	State	Zin	Country		
City	State	Zip	County		
Facility Phone (enter 10 digit #)		Fax (enter 10 digit #)			
Mailing Address (If different than physical address)					
City	State	Zip	County		
L	1		1		

2. Facility Specific Information							
Т	ype of Manufacturer (Check all that apply):						
	Controlled Substance Manufacturer (provide DEA#)						
	Non-controlled Substance Manufacturer						
	Repackager						
Dri	ug Enforcement Administration (DEA) Registration Nu	mber					
В	ackground Questions		Yes	No			
1.	 Have any applicants, partners, or managers had a suspension, revocation, or restriction of a professional license? 						
	If yes,, list and explain on a separate sheet of paper.						
 Have any applicants, partners, or managers been found guilty of a drug or controlled substance violation? 							
If yes, list and explain on a separate sheet of paper.							
3.	Has any owner or officer ever been found guilty of a drug, controlled substance, or moral turpitude violation?						
If yes, attach an explanation in detail, providing the circumstances, places, dates, and outcomes.							
3	3. Contact Information						
Responsible Person for Facility		Phone (Enter 10 digit #)					
Title of Responsible Person for Facility		Email Address					
Contact Person for Regulatory Issues		Phone (Enter 10 digit #)					
Title of Contact Person for Regulatory Issues		Email Address					

4. Additional Information						
Date of Incorporation		Corporate Number			State of Corporation	
Legal Owner Information	n—attach a	additional she	ets as ne	eded	1	
List names, addresses, phon	ie numbers,	and titles of cor	porate offi	cers, partners	, members, managers, etc.	
Name				inter 10 digit #)	Title	
Change of Ownership Ir	formation	1			·	
Previous Name of Legal Owner	r					
Previous Name of Facility						
Previous Pharmacy License # Eff			Effective Date	ective Date of Ownership Change		
Physical Address						
Signature						
I certify that I have receive, read, understood, and agree to comply with state law and rule regulating this licensing category. I also certify that the information herein submitted is true to the best of my knowledge and belief.						
Signature of Owner/Authorized Representative			Date	Date		
Print Name			Print Title	Print Title		
Signature of Responsible Person for Facility			Date	Date		
Signature of Responsible Person for Facility			Print Title	Print Title of Responsible Person for Facility		

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RCW/WAC and Online Web Site Links

RCW/WAC Links

Uniform Disciplinary Act, UDA RCW 18.130 Administrative Procedure Act, APA RCW 34.05 Administrative procedures and requirements, WAC 246-12 Pharmaceutical Manufacturing Laws, RCW 69.38 Pharmaceutical Manufacturing Rules, WAC 246-945-550

Online

Pharmacy Quality Assurance Commission, Web Page