Nevada State Board of Pharmacy 985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 775-850-1440 - bop.nv.gov

OUT-OF-STATE (For locations shipping to the State of Nevada) OUTSOURCING FACILITY (includes 503A, 503B and FDA) INFORMATION AND CHECKLIST

This application cannot be returned by fax or email. We must have an original signature and fee to process.

Failure to submit a complete application will result in significant delays in the processing of the application and issuance of the license.

Please understand we cannot and <u>will not accept</u> incomplete applications. Review the application and return all required fees and documentation with the completed application.

Submission of the application just prior to the deadline date does not guarantee placement on the board agenda.

Please note the application/documentation deadline date is on the board meeting schedule listed on the website. The deadline date is the LAST DAY completed applications will be accepted for that particular board meeting. If the application and all pertaining documentation is not complete and enclosed, the application will be returned.

For a location or name change of an out-of-state OUTSOURCING FACILITY, we only require notification in writing. A new application is only required if changing ownership of 50% or greater.

REQUIRED DOCUMENTS FOR ALL TYPES OF OWNERSHIP You will also be required to submit additional information depending on your ownership type. Details regarding the additional information are included with the application.

Complete all required pages of the application. Must be original signature(s), no copies or stamps.

Registration fee of \$500.00. This fee is non-refundable and non-transferable. The fee is payable by money order or cashier's check only, we do not accept personal checks, business checks, cash or credit cards. If the application is received with a personal check, business check or cash, you will be sent an email asking for the correct fee. If the corrected fee is not received within 21 days, the application and fee provided will be shredded.

<u>Letter of good standing</u> from the state or regulatory board in which your company is located. Download the form from the website under the "New Applications" tab. The forms are available under the *documents for all types of businesses*. An original separate letter from the state or regulatory board also acceptable.

<u>Copy of current registration</u> or license for the outsourcing facility in the state of residence.

Copy of recent state inspection.

Copy of recent FDA inspection.

Copy of Current DEA Registration (if applicable)

REQUIRED INFORMATION FOR ALL TYPES OF OWNERSHIP

An application for an out-of-state OUTSOURCING FACILITY requires Board approval. Upon receipt of the completed application, documentation and fee, your application will be placed on the agenda of the next regularly scheduled Board meeting. The current board meeting schedule is available on the website under the "Calendar of Upcoming Boards & Committee Meetings".

http://bop.nv.gov/board/ALL/Board_Meeting_Schedule/

AN APPEARANCE AT THE BOARD MEETING WILL BE REQUIRED

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy. Please provide the name and license number of the supervising pharmacist on the application.

A license is usually issued and mailed within 20 days from the board meeting date, if approved.

This license is renewed in <u>October of even numbered years</u>, no matter when the license is issued. Fees are not pro-rated.

Please access the applicable laws on the website under "Nevada Statues & Regulations" tab.

If you have any questions, contact the licensing specialist in the Reno office at (775) 850-1440 or by email at pharmacy@pharmacy.nv.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

□ New OUTSOURCIN		king changes) OLIT		
□Ownership Change (Provide current license number if making changes:) OUT□ 503a OR □ 503b Apply as retail pharmacy only.				
you have selected. If L ☐ Publicly Traded Cor	ppe of ownership and complete all r LLC use Non Public Corporation or poration – Pages 1-3 & 4 d Corporation – Pages 1-3 & 5	□ Partnership - Pages 1-3 & 6		
GENERAL INFORM	ATION to be completed by all	types of ownership		
Facility Name:				
Physical Address: _				
City:	State:	Zip Code:		
Telephone:	Fax:			
Toll Free Number: (Required per NAC 639.708)				
E-mail:	Webs	site:		
Supervising Pharmac	cist:	Nevada License #:		
SERVI	CES PROVIDED			
Yes/No				
	Parenteral			
	Sterile Compounding			
	Non Sterile Compounding			
□ □ Mail Service Sterile Compounding				
	Other Services:			
All boxes must be checked for the application to be complete				
An appearance will be	required at a board meeting before	e the license will be issued.		

APPL	ICATION FOR OUT-OF STATE OUTSOURCING FACILITY	Page 2
FEIN	lumber (From FDA application):	
Pleas	e provide the name of the facility as registered with the FDA and the registr	ation number:
Pleas	e provide a list of all DBA's used by outsourcing facility. A separate sheet is	s acceptable.
	ee provide the name and Nevada license number of the supervising pharma e: Nevada License Number:	
	vada business license is not required, however if the OUTSOURCING FACI	
This I	page must be submitted for all types of ownership.	
Withi	n the last five (5) years:	
1)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	Yes □ No □
2)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?	Yes □ No □
3)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry?	Yes □ No □
4)	Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo	

interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes □ No □ If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached.

Yes □ No □

Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

Has the corporation, any owner(s), shareholder(s) or partner(s) with any

contendere to any offense federal or state, related to controlled

substances?

5)

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

The facility must be registered with the FDA as a outsourcing facility from the Board of Pharmacy.	n outsourcing facility (503B) to	o obtain an
Federal and State law require a licensed pharma a registered outsourcing facility. This supervising Board of Pharmacy.	•	0 0 1
Does your outsourcing facility wholesale compou	nded medication for resale?	Yes □ No □
The Law prohibits the resale of compounded meattesting that your medications will be labeled wit outsourcing facilities products will not be resold.	, , , , , , , , , , , , , , , , , , , ,	
Original Signature of Person Authorized to Subm	it Application, no copies or sta	amps
Print Name of Authorized Person	Date	

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

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OWNERSHIP IS A PUBLICY TRADED COMPANY

State of Incorporation:		
Address:		
		Zip:
Telephone:	Fax:	
Contact Person:		
the applicant shall identify the of	ficers of that corporation gistration number issued copy of the SEC report	
Registration number issued:		
Stock Exchange:		<u></u>

Include with the application for a publicly traded corporation

<u>Certificate of Corporate Status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 5

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

Stat	e of Incorp	oration:		
Pare	ent Compai	ny if any:		
City	:		State:	Zip:
Tele	ephone:		Fax:	
Con	tact Persor	n:		
For	any corpora	ation non publicly t	raded, disclose the follo	owing:
1)	List top	4 persons to whom	the shares were issue	ed by the corporation?
	a)			
	,	Name	Address	
	b)			
		Name	Address	
	c)	Name	Addass	
		Name	Address	
	d)	Name	Address	
2)	Provide	the number of shar	res issued by the corpo	oration.
3)	What wa	as the price paid pe	er share?	
4)	What da	ate did the corporat	ion actually receive the	e cash assets?
5)	Provide	a copy of the corpo	oration's stock register	evidencing the above information

Include with the application for a non publicly traded corporation

<u>Certificate of Corporate Status</u> (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 6

OWNERSHIP IS A PARTNE	RSHIP General	Limite	ed
Darto arabia Nama			
Partnership Name:			
Mailing Address:			
City:	State:	Zip Code:	
Telephone Number:	Fax Number:		
Contact Person:			
List each partner and identify whe	ether (G)eneral or (L)imited part	ner and percer	ntage of ownership
<u>Name</u>		G or L	<u>Percentage</u>
List names of 4 largest partners a	nd parcentage of ownership:		
		0/.	
Name:			
Name:			_
Name:		%: <u>_</u>	
Name:		%: <u>_</u>	
List any physician shareholders ar	nd percentage of ownership.		
Name:		<u>%:</u>	
Name:		%: _	
Name:		%.	

OWNERSHIP IS A SOLE OWNER. All information relates to the person listed as the owner.

Owner's Name:					
Business Name:					
Current Business Address:					
City:	State:		Zip Code: _		
Telephone:		Fax: _			
List any physician shareholders and per	centage of ov	wnership).		
Name:				_%:	
Name:				_%:	
Name:				_%:	
Name:				%:	