MAINE
BOARD OF PHARMACY

Manufacturer

Stop **Stop**

If this company manufactures opioid medication products, you must complete the Opioid Prescription Drug Manufacturer (MFO) application using the online services located at https://www.maine.gov/pfr/professionallicensing/professions/board-pharmacy/online-services

***Exception*:**

The manufacturer opioid medication fee does not apply if all opioid medication manufactured is approved by the United States Food and Drug Administration for use only in veterinary medicine. In addition, please visit our website and complete the Opioid Prescription Drug Manufacturer (MFO) form online

Do not return the following informational pages with your application; it is for your information only

Department of Professional and Financial Regulation
Office of Professional and Occupational Regulation
(Mailing address) 35 State House Station, Augusta, ME 04333
(Office location) Gardiner Annex, 76 Northern Avenue, Gardiner, Maine 04345

Office Direct Line (207) 624-8686 or (207) 624-8620
TTY users call Maine relay 711
FAX (207) 624-8637
Web address: www.maine.gov/professionallicensing
Email: pharmacy.lic@maine.gov

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35 State House Station, Augusta ME 04333 Website: www.maine.gov/professionallicensing

INFORMATIONAL

- ✓ Receipt of your application does not constitute entitlement to distribute your product in any manner into Maine until such time as a license has been issued. While applications are logged in as 'pending' this does not mean a license has been issued.

  You must hold an ACTIVE license in order for your prescription products to be shipped into Maine. Your application may be subject to denial or discipline imposed as a condition to licensure if you ship into Maine prior to licensure.

- ✓ Processing time depends greatly on the completeness of your application. Applications that are incomplete and/or missing supporting documents may be returned where you will be required to reapply and pay a new fee. PLEASE FILE A COMPLETE APPLICATION TOGETHER WITH ALL SUPPORTING DOCUMENTS REQUIRED.

- ✓ Please visit our website if you wish to monitor progress. If your application status appears as Pending, this means that your application was received by this office and it is pending or under review. Once reviewed and if everything about your application is complete and complies with requirements, the license will be issued and the status will show as ACTIVE. If incomplete your application may be returned, which may required you to reapply, together with a new fee. We will attempt to work with you to bring an application to completeness for items that are not expected to require a significant amount of time. We suggest you monitor the website for any communications.

- ✓ Please refrain from calling our office to "check" on your application status as these calls only serve to slow our ability to review and process applications. Information regarding the status of applications may be found at the Office of Professional and Occupational Regulation's website www.maine.gov/professionallicensing. We appreciate your thoughtful attention to this request.

- ✓ If there is an urgent need to contact us, please be advised that we will only discuss your application with the contact person named in the application. This is done not only for your protection, but to also avoid complications when multiple individuals are involved and generally lead to miscommunication or misunderstandings. Our goal is to streamline your process, not complicate it.

- ✓ Once your license is issued it is immediately visible online with an "active" status and you may begin to conduct business in Maine.

- ✓ Incomplete applications or documents that have been modified or altered in any way, including use of a white out substance will not be accepted and will be returned. Please write your information legibly.

LAW AND BOARD RULE REFERENCE

Information contained in this application is not a substitute for carefully reviewing applicable laws and rules. You may obtain a copy of the laws and board rules online at www.maine.gov/professionallicensing—Click on "list of licensed professions", click on "Pharmacy" under "Board of Pharmacy Home" click on "Laws & Rules." Notwithstanding, please pay particular attention to the following:

- 32 MRSA Chapter 117 http://www.mainelegislature.org/legis/statutes/32/title32ch117sec0.html
- Board Rules https://www.maine.gov/sos/cec/rules/02/chaps02.htm#392

READY TO SUBMIT YOUR APPLICATON - CHECK, DID YOU COMPLETE THE APPLICATION FULLY AND INCLUDE ALL NECESSARY ATTACHMENTS/ ENCLOSURES:

Do not submit your application unless it is completed fully and all attachments/ enclosures are included.

An incomplete application may be subject to being returned requesting that you file a new fully completed application w/attachments together with a new fee. All fees are non-refundable.

- ⇨Did you respond to all questions and provide a response to all information requested?
- ⇨Did you affix signatures in all areas noted?
- ⇨Payment is enclosed and is it made payable to Treasurer, State of Maine
- ⇨You must submit a copy of the most recent inspection report from the state in which the facility is located. Contact your State of jurisdiction to obtain a copy if you don't have it, OR, if the State of jurisdiction does not inspect facilities, you must attach a letter from the State of jurisdiction that confirms this. Your application cannot be processed solely on the basis of you saying you do not have a current facility inspection or that your State of jurisdiction does not inspect.
- ⇨Is your company's Organizational Chart demonstrating ownership attached?
- ⇨Is a complete list of Jurisdictions licensed attached? *(in the format given in section 6 above)*
- ⇨If there is disciplinary action reported, is a copy of all necessary documents attached?
- ⇨Certificate of Existence or Authority that includes your DBA if applicable from your home state and/or the Maine Secretary of State, whichever applies.

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
COMPANY APPLICATION

APPLICANT INFORMATION (please print)			
NAME OF MANUFACTURER			
FEIN OR SSN			
PHYSICAL LOCATION OF THE MANUFACTURING FACILITY *(STREET)*			
(CITY)	*(STATE)*	*(ZIP)*	*(COUNTY)*
CONTACT ADDRESS			
(CITY)	*(STATE)*	*(ZIP)*	*(COUNTY)*
PHONE # ( )	FAX # ( )		

Maine Board of Pharmacy

Manufacturer (MF)

MF License Fee: $200.00;

(Non Refundable)

Office Use Only:

Check #_____

Amount:_____

Cash #_____

Lic. #_____

Issue Date_____

Exp. Date_____

Office Use Only:

MF1421 - $200.00

PAYMENT OPTIONS:

Make checks payable to "Maine State Treasurer" - If you wish to pay by credit card, fill out the following:

NAME OF CARDHOLDER (please print) *FIRST* *MIDDLE INITIAL* *LAST*

MAILING ADDRESS OF CARDHOLDER (please print)

I authorize the Department of Professional and Financial Regulation, Office of Professional and Occupational Regulation to charge my ☐ VISA ☐ MASTERCARD ☐ DISCOVER ☐ AMERICAN EXPRESS The following amount: $_____

□ **I understand that fees are non-refundable**

Card number: Expiration Date *mm* / *yyyy*

SIGNATURE **DATE**

SECTION 1: TYPE OF APPLICATION

□ **Initial Application**

□ **Change of Ownership - Important, please read -** Reference 32 MRSA §13752, Sec. 3. A license is not transferrable to another owner and is subject to a new application and license under the new owner(s) before operation may begin and product shipment into Maine.

□ **Maine License No. of Prior Owner(s)** _____ **Exp. Date** _____

Date Ownership Changed or Anticipated: _____
(You may be requested to demonstrate legal proof of the date of change, please be accurate.)

□ **Change of Location -** A license is not transferrable to a new location and is subject to a new Application. The new location must hold an ACTIVE license before operation can begin at the new Location. *The former location license will be terminated.*

Maine License No. for Prior Location _____ Exp. Date _____

Anticipated Date of Location Change: _____

SECTION 2: APPLICATION CONTACT PERSON
The Owner of the entity may name a contact person assisting in the application process, however, the Owner is responsible for all information required for this application and all supporting documents required.

Last Name	First Name	Middle Name
Contact Person's Title and email address		

Name of Manufacturer	
Manufacturer Phone Number / Fax Number	24-Hour Phone Number
( ) ( )	( )
E-mail Address—License will be emailed to this address	Web Address
DEA # *(Required pursuant to 32 MRSA §13758 (4)), if not applicable, you must provide a written statement)*	Date Executed
FDA # *(Required pursuant to 32 MRSA §13758 (4)), if not applicable, you must provide a written statement)*	Date Executed
All Trade Names or Business Names of the Manufacturer	

SECTION 3: FACILITY CONTACT PERSON

Last Name	First Name	Middle Name
Title		

Address	City	State	Zip Code

24-Hour Telephone Number	E-mail Address of Facility Contact

SECTION 4: OWNERSHIP. Please check one and complete the appropriate block below.

□ **Sole Proprietor *(complete section A)***

□ **Partnership *(complete section B)*** - If your partnership consists of 2 or more corporations, you must submit a list of officers and an organizational chart.

□ **Corporation and Limited Liability Company *(complete section C)*** - If you are a corporation, you must **submit a Certificate of Existence from the State of origin**.
For Corporations not organized under Maine law, a Certificate of Authority from the Maine Secretary of State is required including assumed name or DBA. For assistance, call (207) 624-7752. Please be aware the application to file for a certificate of existence is not evidence of having been issued a Certificate of Authority.

Section A - Sole Proprietor: (Please type or print legibly)			
Owner Last Name	First Name	Middle Name	
Social Security Number			
Name of Business Entity			
Contact Address	City	State	Zip Code
Telephone Number	Fax Number		
( )	( )		
E-mail Address Website Address			

SECTION 4 (Continued):

Section B - Partnership: List the name and address of each partner (please type or print legibly). *Please see Chapter 12, Sec. 2(5)(A)* (If you need more space please use separate sheet)			
PARTNERSHIP INFORMATION:			
Name of partnership			
Contact Address	City	State	Zip Code
Telephone Number		FEIN Number	
( )			
E-mail Address			

NAME AND CONTACT INFORMATION OF EACH PARTNER

Person Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		( )	

Person Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		( )	

Person Last Name	First Name	Middle Name	
Contact Address	City	State	Zip Code
E-mail Address		Telephone number	
		( )	

Section C - Corporation Ownership: Please include an organizational chart. (Please type or print legibly) *Please see Board Rule, Chapter 12, Sec. 2(5)(B)*			
Name of Corporation			
Assumed Name (d/b/a)			
Name of Parent Company, if any			
FEIN # of Parent Company, if any			
Applicant Contact Address of Corporation	City	State	Zip Code
Applicant Physical Address of Corporation	City	State	Zip Code
Applicant Telephone Number applicant			
( )			
E-mail Address for contacting company			

Registered Agent Name for Maine			
Contact Address for Registered Agent *If different from Corporation*	City	State	Zip Code
Physical Address for Registered Agent *If different from Corporation*	City	State	Zip Code
Registered Agent Email Address/Web Address	Telephone		
	( )		

Name of Designated Officer - Must be an officer of the corporation applying for licensure			
Mailing Address of Representative	City	State	Zip Code
Telephone Number	E-mail Address		
( )			

SECTION 4-C (Con't): CORPORATION OWNERSHIP
Please see Board Rule, Chapter 12, Section 2(5)(B).
Is this corporation's stock traded on a major stock exchange and not over-the-counter

YES ☐ NO ☐ If, no complete the section below—List the name and contact address of each shareholder owning 10% or more of the voting stock of the corporation, including over-the-counter stock. Use a separate sheet of paper if needed.

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
( )		( )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
( )		( )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
( )		( )	

Name			
Address	City	State	Zip Code
Email Address		Telephone Number	
( )		( )	

SECTION 4-C (Con't): CORPORATE OFFICER(S) AND DIRECTOR

1. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

2. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

3. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

4. Last Name	First Name	Middle Name	
Title			
Address	City	State	Zip Code

SECTION 5: DISCLOSURE

Has any state or territory of the U.S., province/territory of Canada, or any other jurisdiction **ever** denied to **this entity** an application for license, certificate or registration, **or** taken any disciplinary action in that jurisdiction (including, but not limited to, warning, reprimand, fine, suspension, revocation or restrictions in permitted practice, probation with or without monitoring)? 1. List the jurisdiction(s) that denied your license or issued discipline and date of action: State/Jurisdiction_____ Date _____ State/Jurisdiction_____ Date _____ State/Jurisdiction_____ Date _____ 2. Attach with this application a copy of the consent agreement or decision and order for each of the above, with this application. 3. Attach with this application - Describe, on a separate sheet of paper, a detailed explanation in your own words, the nature of the incident.	□ No □ Yes, Complete requested information AND attach with this application **all** information requested; application will not be accepted otherwise.
Has the US Drug Enforcement Administration (DEA) ever denied registration or had a DEA Registration modified, restricted, suspended or revoked? 1. Attach with this application - Copy of the official document related to the DEA action taken against entity. 2. Attach with this application - Describe, on a separate sheet of paper, a detailed explanation in your own words, the nature of the incident.	□ No □ Yes, as stated in the block above attach all information requested with this application
Has this entity ever been issued a citation, warning letter or untitled letter by FDA or similar action taken by any governmental board? 1. Attach with this application - Copy of the official document related to the FDA action taken against entity. 2. Attach with this application - Describe, on a separate sheet of paper, a detailed explanation in your own words, the nature of the incident.	□ No □ Yes, as stated above attach all information requested with this application

SECTION 6: LIST OF JURISDICTIONS IN WHICH YOU HOLD OR HAVE EVER HELD A MANUFACTURER LICENSE.

On a separate sheet, list each state or jurisdiction the applicant has at any time held a pharmaceutical license, including controlled substance licenses. **The information must include the following in the same format please:**

State, Territory, Country	License Number & Lic Type	Date Issued	Expiration Date	Was discipline ever imposed? Yes / No

FORM: For your convenience a form to report this information is available online from our applications and forms section entitled "Reporting Jurisdictions of Licensure."

If discipline was imposed, you **must attach with this application** a copy of the consent agreement, order or legal document issued.

SECTION 7: NOTICE REGARDING INSULIN PRODUCT REGISTRATION FEE

☐ Check here to demonstrate you have read this notice.

NOTICE REGARDING INSULIN PRODUCT REGISTRATION FEE:
Ref. 32 M.R.S.A. § 13800-D. Insulin product registration fee

A Manufacturer that produces insulin that is sold, delivered or distributed in the State of Maine shall pay an annual registration fee of $75,000 to the board at the time of renewal in addition to any license renewal fee required to be paid by the manufacturer. (licenses expire December 31 annually)

Exception: A manufacturer whose aggregate total of insulin sold, delivered or distributed in this State does not exceed 500,000 units of insulin in the year in which a registration fee is due is not required to pay the registration fee. To qualify for the exception, a manufacturer must demonstrate to the board, by January 31st of the year following the year in which the registration fee is due, that the aggregate total of insulin produced by the manufacturer that was sold, delivered or distributed within this State in the year in which the manufacturer seeks to claim the exception did not exceed 500,000 units

Example: Registration due December 31, 2022, request for an exception must be submitted by January 31, 2022, and so on.)

Note: This page must be returned with the application.

SECTION 8: MANUFACTURERS OF OPIOID MEDICATION

☐ **Check here to demonstrate you have read this notice.**

NOTICE REGARDING MANUFACTURERS OF OPIOID MEDICATION:

If this entity manufacturers opioid medication products you must complete the Opioid Prescription Drug Manufacturer (MFO) application online. You must submit this manufacturer (MF) application before applying online for the Opioid Prescription Drug Manufacturer license.

Once the Board has received your application for the MF license, a pending license number will be assigned and be available for you to obtain using this link
https://www.pfr.maine.gov/almsonline/almsquery/SearchCompany.aspx
You may then apply online for the MFO registration using the following link
https://licensing.web.maine.gov/cgi-bin/online/licensing/begin.pl?board_number=4380

A Manufacturer of opioid medication (MFO) will be assessed for a total fee of $55,000. IF the entity only manufactures an opioid medication(s) that is approved by the United States Food and Drug Administration for use only in veterinary medicine, the $55,000 assessment does not apply, but the MFO registration is still required.

A Manufacturer of opioid medication (MFO) that sells, delivers, or distributes an opioid medication within Maine shall pay an annual product registration fee of $250,000 to the board at the time of renewal (licenses expire December 31 annually).

Exception: A manufacturer that does not sell, deliver or distribute 2,000,000 million or more units of an opioid medication within Maine in the year in which a registration fee is due the manufacturer is exempt from the product registration fee. To qualify for the exception, the manufacturer must demonstrate proof to the board, by January 31st of the following year in which the registration fee is due.

Example: Registration due December 31, 2020, request for an exception must be submitted by January 31, 2021, and so on.)

Note: This page must be returned with the application.

SECTION 9: Opioid Medications Manufacturing—Statement/Affirmation

1) Does this entity manufacture opioid medications for distribution in the state of Maine?

Check: ☐ **YES —You must complete the MFO form for the Opioid Prescription Drug Manufacturer. (Once your MF (Manufacturer) application is received by this office, you will be sent the tracking Pending License number and Access Code to the email address provided on this application, which will be needed to access the online MFO form that you must complete.**

☐ **No**

A Manufacturer of opioid medication (MFO) will be assessed for a total fee of $55,000.

IF the entity only manufactures an opioid medication(s) that is approved by the United States Food and Drug Administration for use only in veterinary medicine, the $55,000 assessment does not apply, but the MFO form must be completed

SECTION 10: APPLICANT'S CERTIFICATION AND SIGNATURE

Read the statement below and sign where indicated as your certification of the information provided on this application. Applications that are incomplete, altered (including use of any white out), defaced, or compromised will not be accepted and will be returned. This includes, but is not limited to, unanswered questions, lack of appropriate signature, information is illegible, missing required supporting documents, and/or missing or wrong fee.

By my signature, I hereby certify that the information provided on this application is true and accurate to the best of my knowledge and belief. By submitting this application I understand that the Maine Board of Pharmacy will rely upon this information for issuance of my license and that this information is truthful and factual. I further understand that sanctions may be imposed, including denial, suspension or revocation of my license, if this information is found to be false.

Printed Name of Owner or Officer of the Entity *(32 MRS §13758(4))*	Title
Signature	Date