MINNESOTA BOARD OF PHARMACY

Protecting the Public Since 1885 | pharmacy.board@state.mn.us

335 Randolph Ave., Suite 230 | St. Paul, MN 55102

Drug Manufacturer/Outsourcing Facilities New Application - *Instructions*

For Resident and Non-Resident Applicants

Licensure as a manufacturer is required for all parties involved in the manufacturing of a drug product. This includes but is not limited to virtual manufacturers, contract manufacturers, repackager, and labelers. The exception is if the manufacturer is located outside of the United States or its territories. **Manufacturers who distribute the drugs of *other manufacturers* must also be licensed as drug wholesalers.**

Application fees

- A Non-Opiate Manufacturer and a Non-Opiate Outsourcing Facility application fee is $5,500.
- An Opiate Manufacturer and an Opiate Outsourcing Facility application fee is $55,500.

Licenses are mailed to the facility's physical address. The completed application, supporting documentation, and correct payment must be received by the Board before the application can be processed. All fees are non-refundable. State of Minnesota Tax ID: 4405717, Federal ID: 41-6007162.

Mail the completed renewal form, documents, and payment to Minnesota Board of Pharmacy, 335 Randolph Avenue, Suite 230, St. Paul, MN 55102. Checks should be payable to the Minnesota Board of Pharmacy. All payments are non-refundable.

Checklist for All Applicants

All applicants are required to complete and submit the following information:

√ **Application.** Complete the application in its entirety and submit with original signatures and all documents. Do not leave any leave blanks. If an item or question is not applicable, indicate N/A.

√ **Ownership forms and supporting documents.** Submit the following forms to provide information about the applicant licensee's ownership.

- **Secretary of State - NON-RESIDENT ONLY.** Submit a current Certificate of Good Standing issued by the state in which the facility is located, obtained within the last 24 months.
- **Minnesota Secretary of State - RESIDENT ONLY.** Submit a current Certificate of Good Standing from the Minnesota Secretary of State. For resident pharmacies operating under an Assumed Name, also submit a Certificate of Assumed Name Registration."
- **Organizational Chart.** Provide an organizational chart that shows the multi-levels of ownership and the percentage owned. Individual shareholders, partners, members or parent entity of applicant licensee must be disclosed in full.

√ **List of Officers.** The officers must be identified by name, title and percentage owned if applicable.

√ **List of all Shareholders.** Include the shareholder's name, title, address, city, state, and zip code along with their ownership percentage.

√ **List of dosage forms** proposed to manufacture, re-label, or repackage.

√ **FDA Registration.** Provide proof of current FDA Drug Establishment Registration. You must have an FDA registration or we will not issue or renew a license. A printout of your current FDA registration showing the expiration date from the FDA clearing house is acceptable.

- Outsourcing facilities must hold a current FDA registration as an Outsourcing facility and provide proof of such.

√ **Workman Compensation Requirements** (RESIDENTS ONLY). Minnesota Statute 176.182 requires the applicant to provide acceptable proof of compliance with the workers' compensation coverage provisions before the Board of Pharmacy shall issue a license.

√ **Current Home State License** (NON-RESIDENTS ONLY). A copy of your current license/registration from the state your facility is located, or a letter from your home state explaining that your state does not require a license.

√ **Inspection Report** (NON-RESIDENTS ONLY). Provide a copy of a full inspection report and any corrective actions on deficiencies or observations made during the inspection, with all related documents, from your state or the FDA, obtained within the last 24 months. Please note that 'Notices of Inspections' and/or Self-Inspections **do not** meet the Board's inspection requirements.

Additional Requirements for Virtual Manufacturers

Virtual manufacturers of legend and/or OTC drugs are required to be licensed as a manufacturer (MN Stats. § 151.252). A virtual manufacturer is an entity that holds the approved New Drug Application (NDA) or the Abbreviated New Drug Application (ANDA) for a drug and contracts with a contract manufacturing organization (CMO) for the physical manufacture of the drug.

In addition to the checklist items under checklist for all applicants, the following must be included.

- √ Provide the Minnesota license numbers of all contract manufacturers and 3PLs on the application.
- √ Provide a business summary including all contract manufacturers and distributors of the drugs.
- √ An FDA issued Labeler Code is a form of FDA registration and is required for virtual manufacturers.

Additional Requirements for Outsourcing Facilities

In addition to the checklist items under checklist for all applicants, the following must be included.

- √ Outsourcing facilities must be licensed as wholesalers. Provide the Minnesota wholesaler license number on the application, or include the Minnesota Drug Wholesaler application along with this submission.
- √ Outsourcing facilities dispensing patient specific prescriptions must be licensed as a non-resident pharmacy. Provide the Minnesota pharmacy license on the application.
- √ Outsourcing facilities must hold a current FDA registration as an Outsourcing Facility and provide proof of such.
- √ Inspection reports conducted to current good manufacturing practices that has occurred while the facility is actively engaged in production of product, **and** within the 24 months preceding receipt of the application by the board. This inspection should be issued by the appropriate regulatory agency of the state in which the facility is located *or* by the FDA MS 151.252 Subd 1a (g).
- √ Corrective actions on deficiencies or observations made during the inspection with all related documents.

Officer Forms

Officer Form FAC-002 is available to report officers, and Officer Change Form is available to report a change in officers. Officer changes should be reported to the Board within 30 days of change.

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Drug Manufacturer New Application – *Resident and Non-Resident*

Facility Type (Choose one of the two types below)

☐ Non-Opiate Manufacturer or Non-Opiate Outsourcing Facility (fee $5,500) ☐ Opiate Manufacturer or Opiate Outsourcing Facility (fee $55,500)

Opiate manufacturers that own more than one facility are only subject to one $55,500 fee. If this applies, list the license numbers of all facilities under one ownership and indicate which facility will pay the $55,500 fee. All other facilities listed below must apply separately and pay the appropriate fee.

Name of Facility to appear on license	If DBA, Legal Name	MN Tax ID	Federal Tax ID	FDA Registration	DEA Number

Physical Address					City	Mailing Address				City
State	Zip	Phone	Square Footage	Effective Date of Change		State	Zip	Phone	Email Address	

Hours of Operation

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Open 24 Hours
							☐

Categories

Check each category you will sell drugs to:

- ☐ Home Health Agency
- ☐ Dentist
- ☐ Pharmacy
- ☐ Nursing Home
- ☐ Medical Doctor
- ☐ Veterinarian
- ☐ Wholesaler
- ☐ Other _____

Check all categories of drugs you propose to handle:

- ☐ Human Prescription
- ☐ Human Non-prescription (OTC)
- ☐ API
- ☐ Veterinary Prescription
- ☐ Veterinary Non-prescription (OTC)
- ☐ Other: _____
- ☐ Controlled Substances
- ☐ Medical Gases
- ☐ Human/Vet drug products made by Outsourcing Facility

Does the applicant have the required equipment necessary to comply with good manufacturing practices? ☐ YES ☐ NO ☐ N/A

Individual Completing Application

Must be authorized to discuss application materials.

Name	Title	Phone	Email

Ownership Contact Information

Person authorized to speak on behalf of the owner.

Name	Title	Phone	Email

Facility Contact Information

Contact Name	Phone	Email

Outsourcing Facilities

Outsourcing facilities must also be licensed as wholesalers. Minnesota wholesaler license number _____. Enter "Pending" in the blank to signify that you have submitted an application.

Outsourcing facilities dispensing patient specific prescriptions must also be licensed as a non-resident pharmacy.

Minnesota pharmacy license number _____.

Virtual Manufacturer

Provide the MN License Numbers for the Contract Manufacturers and 3PLS you use.

Name	License #	Name	License #

Qualifications of personnel: (production and quality control)

Name	Qualifications	Position

Ownership Information

Owner (Legal Name)	☐ LLC ☐ S Corporation ☐ Limited Partnership Publicly Traded ☐ ☐ Corporation ☐ Partnership ☐ Proprietorship				
Address	City	State	Zip	Email Address	Phone Number
State of Incorporation		Number of Shares/Stock Issued			

Read each statement carefully, following the instructions below.

- Answer the questions on the next page with the correct ownership type, i.e., if the facility is an LLC, answer only the questions below the, "On behalf of the corporation…".
- Review and attest to each statement below by marking YES or NO.
- If you answer YES to any of the questions that require additional explanation, provide a detailed explanation on a separate document.

On Behalf of the Corporation, S Corporation, or Limited Liability Company (LLC):

Yes	No	
☐	☐	Has the applicant facility previously applied for a license to operate a facility in Minnesota?
☐	☐	Has the applicant facility applied for a license to operate a facility in any other state?
☐	☐	If yes above, was the application denied by the Board of Pharmacy or appropriate licensing agency? **If the application was denied, attach a separate document with an explanation.**
☐	☐	If a license was granted, was it later suspended, revoked, or placed on probation?
☐	☐	In connection with any violations, did the licensing agency issue any warning or reprimands? **If yes, attach a separate document indicating nature of violation, an explanation of why it happened, and a copy of the written findings/warning(s)/reprimand(s).**

On Behalf of a Partnership or Sole Proprietor, Has the Individual(s)

Yes	No	
☐	☐	Been convicted of a felony in any court? **If yes, provide all related documentation and/or an explanation on a separate sheet.**
☐	☐	Habitually indulged in the illegal use of narcotics, stimulants, or depressant drugs; or habitually indulged in intoxicating liquors in a manner which could cause incompetence in the operation of the facility? **If yes, attach a separate document with an explanation.**
☐	☐	Been convicted of theft of drugs or the unauthorized use, possession, or sale thereof? **If yes, attach a separate document with an explanation.**
☐	☐	Previously applied for a license to operate a facility in Minnesota?
☐	☐	Applied for a license to operate a facility in any other state?
☐	☐	If yes to the above, was the application denied by the Board of Pharmacy or appropriate licensing agency? **If yes, attach a separate document with an explanation.**
☐	☐	If a license was granted, was it later suspended, revoked, or placed on probation?
☐	☐	In connection with any violations, did the licensing agency issue any warning or reprimands? **If yes, attach a separate document indicating nature of violation and an explanation of why it happened.**

Insurance Coverage for Facilities Residing in Minnesota

Minnesota Statute 176.182 requires the applicant to provide acceptable proof of compliance with the workers' compensation coverage provisions before the Board of Pharmacy shall issue a license.
If your facility is not located in the state of Minnesota, do not complete this section. **If your facility is in Minnesota, please check the appropriate box below.**

- ☐ This facility does not employ anyone and therefore, will not supply workers' compensation coverage documents.
- ☐ This facility is self-insured and has attached a **Certificate of Exemption.**
- ☐ This facility has paid, or compensated employees and has attached a **Certificate of Insurance.**
- ☐ This facility has paid, or compensated employees and is supplying the insurance company information:

Insurance Co. Name	Policy Number	Policy Expiration Date	Address	Phone Number

The data you supply on this form will be used to assess your qualifications for licensure. You are not legally required to provide this data, but we will not be able to grant the license without it. This data will constitute a public record, when the licensure is granted, and, at that time, copies may be issued to anyone.

Acknowledgment

I have read the above statement and I agree to supply the data on this form with full knowledge of the information provided in that statement. In addition, I, the undersigned, do hereby certify that all the information above is true and correct and that the firm will be operated in compliance with all applicable laws and regulations.

_____ _____

Signature of Owner, Partner, Managing Officer, or Authorized Individual — Date