

Per Rule §15-1-14.4.2 renewal applications must be **RECEIVED** in our office by June 15th in order to allow time to process by June 30th. If a completed application for renewal is not received in the Board office on or before June 30 of the year in which it expired, the license is expired. Renewal applications received after June shall require the payment of a late fee in the amount of \$150.00 in addition to the renewal fee. Renewal applications not received by the first day of August each year shall require the payment of a reinstatement fee of \$250.00 in addition to the renewal fee.

West Virginia Board of Pharmacy

1207 Quarrier St. 4th Floor

Charleston, WV 25301

APPLICATION FOR LICENSE PERMIT OR RENEWAL AS A MANUFACTURER

(Includes Traditional Manufacturer, Virtual Manufacturer, and 503B Compounding Manufacturer)

(WV Code § 30-5-25)

July 1, 2024 to June 30, 2026

Current name and address: _____ Old name, address, and license #: _____ Check here if name or address change
(Address change requires new application & fee)

Check here if ownership change

(Ownership change requires new application & fee)

City _____ County _____ State _____ Zip _____

License # MR Email Address: _____ DEA# _____ Phone # _____

Attach a list of current owner, partners, or corporate officers and titles.

Are you licensed/registered by the FDA?

If yes, as a Manufacturer _____ or 503b Outsourcing Facility _____?

If Manufacturer, Please ATTACH a copy of your current FDA registration.

If 503b Outsourcing Facility, Please ATTACH a copy of your current FDA registration, please ATTACH a copy of FDA inspection within the last 5 years. Also, ATTACH a copy of any FDA 483 or warning letter associated with that inspection and responses. (If 503b additional fee of \$150.00 is required for sterile compounding permit)

Attach a list of products to be manufactured, packaged or repackaged.

Check here if handling Controlled Substances. Circle applicable drug schedules: C-I C-II C-III C-IV C-V

Name of person authorized to sign for controlled substances _____

Pharmacist-In-Charge _____ RPh# _____ Phone _____

Address _____ City _____

State _____ Zip _____ County _____

NOTE: If a pharmacist is not employed, give the following information on person in charge:

Chief Science Officer/Person-In-Charge _____ Phone _____

Address _____

City _____ State _____ Zip _____ County _____

I hereby certify that the answers given in this application are true and correct to the best of my knowledge. I understand that approval of this application will only extend to those products listed and that the products and personnel approved thereby are not subject to change except on approval by the Board of Pharmacy of a new application.

Annual Fees: (Biennial Renewal-Listed fees should be doubled)

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NOTE: Every initial application for a permit shall be accompanied by the required fee of \$500.00. The renewal of such permit or license shall be \$500.00 ANNUALLY. You must attach copies of your State License and most current inspection report as well as copies of your federal and state controlled substance registration, if shipping controlled substances.

If handling Controlled Substances, an additional fee for the Controlled Substance Handling Permit of **\$50.00** is required, for a total fee of **\$550.00**.

If performing sterile and/or nuclear compounding additional **\$150.00 (annually)** is required.

Signature of Authorized Individual

Title

Date