MISSISSIPPI BOARD OF PHARMACY

6360 I-55 North, Suite 400
Jackson, MS 39211
licensing@mbp.ms.gov

Office: 601-899-8880
Fax: 601-899-8851
www.mbp.ms.gov

DRUG FACILITY PERMIT APPLICATION CHECKLIST

Check if Complete	REQUIRED ITEMS	Office Use Only
	➢ Completed Application (ALL required fields, attachments and fees must be included for the application to be considered complete)	
	➢ Submit a brief description of services offered	
	➢ Completed Fingerprint Card, Background Questionnaire, Verification Form and Signed and Notarized Affidavit for the Designated Representative	
	➢ Copy of your current home state license/permit	
	➢ Most recent inspection report (should your state no longer perform inspections on your facility type, please submit something from your home state detailing this)	
	➢ List of states where licenses/permits/registrations are held	
	➢ Copy of DEA registration (if applicable)	
	➢ Documentation of current FDA registration (Manufacturers and Re-Packagers only)	
	➢ Evidence of Surety Bond or Letter of Credit	
	➢ Third Party Logistics Providers and Virtual Entities must provide a list of all trading partners they provide service for. This will be a list of 3PLs or contract manufacturers you do business with or plan to do business with.	
	➢ Education, Training, experience or combination of these are required of employees to assure assigned functions are performed in a manner that ensures prescriptions drug quality, safety, and security will always be maintained . Attach SOP or training narrative with details.	
	➢ Appropriate Signatures must be affixed	
	➢ PAYMENT OF FEES: (Fees are NON-REFUNDABLE) • $500 Application Fee • $50 Controlled Substances Permit Fee (If Applicable) • $40 Background Check Fee for Designated Representative • Make checks payable to MISSISSIPPI BOARD OF PHARMACY • Check may be submitted cumulatively or separately. • A LATE FEE of $250 will be assessed on any application received after December 31, 2018.	
	➢ THE ENTIRE APPLICATION (ALL PAGES INCLUDING FINGERPRINT DOCUMENTS) MUST BE MAILED TO: MISSISSIPPI BOARD OF PHARMACY Attention: Ann Spence, Licensing Division 6360 I-55 North, Suite 400 Jackson, Mississippi 39211 For Questions Please Email: licensing@mbp.ms.gov	

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DEFINITIONS OF THE TYPES OF DRUG FACILITY PERMITS

WHOLESALE DRUG DISTRIBUTOR (WDD)

A company engaged in the distribution of their own product. They own, house and ship their product in their name or a product licensed to them by another company. A Wholesale Drug Distributor has product manufactured under a contract or trade agreement with a manufacture or purchases product from another company to house and ship. They must be registered with the FDA. State license required in home state and all states they ship product to. If they ship control substance product, must have a DEA registration. MUST FOLLOW DSCSA REGULATIONS.

MANUFACTURER

Manufactures product for themselves or other companies under contract or trade agreement. Must be registered with the FDA. Must be registered with the DEA if they produce control substance product. License in home state required. MUST FOLLOW DSCSA REGULATIONS.

THIRD PARTY LOGISTICS (3PL)

This facility ships pharmaceutical product for other companies. Must have contract or trade agreement with each company they ship for. This facility does not take ownership of product, but does store product, control product inventory and shipping/receiving records for other pharmaceutical companies. MUST FOLLOW DSCSA REGULATIONS.

RE-PACKAGER

This facility packages product for other companies under a contract or trade agreement and does not take ownership of the product. Must be registered with the FDA. MUST FOLLOW DSCSA REGULATIONS.

VIRTUAL

A facility that is registered with the FDA, owns or licenses a product, but never receives the product into their facility. They contract to have product made by an FDA registered pharmaceutical company. They also contract to have it shipped by an FDA registered third party logistics company. They must be licensed in all states they have product shipped to and their home state. They are required to maintain an office with full-time employee(s), and keep records on their products, have SOPs and handle their product complaints and adverse events. MUST FOLLOW DSCSA REGULATIONS.

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DRUG FACILITY PERMIT

Check **ONLY ONE** per application – (USE SEPARATE APPLICATION PER PERMIT TYPE):

- ☐ -Manufacturer
- ☐ -Virtual Manufacturer
- ☐ - Virtual Wholesaler
- ☐ -Re-packager
- ☐ -Wholesale Drug Distributor (WDD)
- ☐ -Third Party Logistics Provider (3PL)
- ☐ -Veterinary Drug Distributor
- ☐ -Reverse Distributor

Application for NEW Drug Facility Permit

ALL Changes to existing Drug Facility Permits will require an amendment to permit document. This is attached to the back of this application.

Purpose of Application:

☐ - **New**

To change the location/address, facility name, designated representative or ownership, you will need to submit an amendment to permit application along with applicable fees. This document is included at the end of this document and is also available on our website under applications and fees.

http://www.mbp.ms.gov/Documents/Change_Form_For_Permit_8_2018.pdf

Entity Name:

_____

Permit Period:
January 1, 2020
through
December 31, 2020
$500.00 ANNUALLY

Permit Period is January 1st through December 31st Annually. Fee $500.00

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- Any answers, explanations, or omissions found to be false or deceptive may result in the Board denying issuance of, or permanent revocation of, your permit in the State of Mississippi.

- Type or print answers to all questions. If more space is required, attach supplemental page(s) identifying each item corresponding to the application.

Section 1: LOCATION OF FACILITY REQUESTING PERMIT

☐ **Within Mississippi** ☐ **Outside of Mississippi** **(Current Permit # _____if applicable)**

Section 2: APPLICANT (BUSINESS ENTITY) INFORMATION

Name of Business:

Circle One:
Sole Prop / Inc / LLC / Other:_____

Federal Tax ID#: **(REQUIRED)**

DEA #:

FDA #: **(REQUIRED)**

NABP #:

FDA # only required for Re-Packagers and Manufacturers. Provide all numbers that apply to the facility.

DBA/Trade Name(s) (If applicable): (Please list **ALL** Trade Names used. Use a separate, attached page if necessary.)

Name of Entity's Parent Company: (If the corporate structure extends past a parent, attach complete details of the corporate structure.)

Entity Physical Address: (Including City, State & Zip)

Entity Phone #:

Fax #:

Mailing Address (If different): (Including City, State & Zip)

State in which the Entity is incorporated:

Website URL:

Corporate Offices Direct Telephone #:

Does the Entity hold any other licenses, registrations or permits in Mississippi? (If yes list details – List all on separate sheet if needed.)

Section 3: DESIGNATED REPRESENTATIVE CONTACT INFORMATION (REQUIRED)

(This cannot be a call center, etc.)

Name:

Social Security #:

Direct Phone #:

Cell Phone #:

Fax #:

E-mail Address:

***AN INDIVIDUAL CAN BE A "DESIGNATED REPRESENTATIVE" IN ONLY ONE FACILITY.**

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Section 4:	ENTITY OWNERSHIP INFORMATION *(REQUIRED) [If corporately owned, provide details of corporate structure.]*	
Name	**Title**	**Address**

Section 5:	FACILITY/APPLICANT BACKGROUND INFORMATION	
1)	Has the Drug registration or permit of the facility/applicant under any local, state or federal law ever been suspended or revoked? (If yes, attach an explanation and certified copies of all documents and records.)	☐ **YES** ☐ **NO**
2)	Has the Applicant ever been found liable in any lawsuit or arbitration proceeding involving allegations of fraud, illegal or dishonest activities? *(Attach specific details separately.)*	☐ **YES** ☐ **NO**
3)	Has the Applicant had a business relationship terminated for any fraudulent, illegal or dishonest activities? *(Attach specific details separately.)*	☐ **YES** ☐ **NO**
4)	Third Party Logistics Providers and Virtual Entities must provide a list of all trading partners they provide service for. (Contract Manufacturers and 3PLs)	**ATTACH**

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5) Has the Applicant, parent company or any company or organization controlling operations experienced any data security breaches or HIPAA security breaches? (If YES please attach all pertinent information concerning any data security breach. Any future data security breach must be reported immediately to the Mississippi Board of Pharmacy.)	☐ **YES** ☐ **NO**
6) **Facility Sells Drugs To:** [ ] Community Pharmacies [ ] Hospital Pharmacies [ ] Wholesalers [ ] Distribution Center for Multiunit (Chain) [ ] Distribution Center for Pharmacy Corp. [ ] Broker/Jobber [ ] Reverse Distributor [ ] Other (specify)_____	
7) **Types of Drugs Distributed:** [ ] Controlled Substances [ ] Non-Controlled Substances [ ] DEA Regulation No._____	
8) Has the Applicant ever been denied issuance of, or pursuant to disciplinary proceedings, refused renewal of a license, registration or permit by any Board or agency in Mississippi or any other state? (If yes, please attach an explanation and certified copies of all documents and records.)	☐ **YES** ☐ **NO**
9) Have any of the owners, partners of the firm, or officers of the corporation ever been convicted of any crime under the laws of the United States, Mississippi or any other State pertaining to the manufacturing, distribution, sale or dispensing of drugs or narcotics? (If yes, please attach an explanation and certified copies of all documents and records.)	☐ **YES** ☐ **NO**
10) What education, training, experience, or combination of these are required of employees to assure assigned functions are performed in a manner that ensures prescriptions drug quality, safety, and security will be maintained at all times as required by law and regulation? (Attach narrative or SOP with details.)	**ATTACH**

Section 6: OTHER REQUIRED DOCUMENTATION

1) Provide the most recent inspection reports for physical facility.	**ATTACH**
2) Provide a list of all states in which licenses/permits/registrations are held. (Include numbers, expiration dates, status, etc.)	**ATTACH**
3) Provide a copy or documentation of your most current FDA registration. (This applies to Manufacturers and Re-packagers only)	**ATTACH**
4) Provide a brief description of services offered by Facility. **(Required for ALL applicants.)**	**ATTACH**

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Section 7: SURETY BOND OR LETTER OF CREDIT	
TITLE 30: PROFESSIONS AND OCCUPATIONS **Part 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS** 2. B. Provide evidence of a surety bond in the amount of $100,000 (or $25,000 for an entity whose annual gross receipts total $10,000,000 or less for the previous tax year) or other equivalent means of security acceptable to the State. (Attach evidence of Surety Bond, Letter of Credit or other equivalent means of security.)	**ATTACH**

Section 8: REQUIRED BACKGROUND CHECK	
TITLE 30: PROFESSIONS AND OCCUPATIONS **Part 3001: MISSISSIPPI PHARMACY PRACTICE REGULATIONS** 2. C. Submit Drug Facility Background Check Packet for Designated Representative, including fingerprinting. (Attach completed Fingerprint Card, Background Check Affidavit Questionnaire / Fingerprint Verification and return with application along with a Background Check fee of $40.00 for DESIGNATED REPRESENTATIVE.)	**COMPLETE ENTIRE BACKGROUND PACKET AND ATTACH FINGERPRINT CARD AND $40 BACKGROUND FEE. TO REQUEST FINGERPRINT CARDS, PLEASE EMAIL:** **Licensing@mbp.ms.gov**

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(COMPLETE IF APPLICABLE / ATTACH PROOF OF DEA REGISTRATION)

APPLICATION FOR REGISTRATION TO HANDLE CONTROLLED SUBSTANCES

January 1, 2020 – December 31, 2020
FEE - $50.00

Name of Business:	**Federal Tax ID#:**		**DEA #:**
Street Address:			
City:	**State:**	**Zip:**	**County:**
Applicant's Signature:			
Print or Type Name:			

OFFICE USE ONLY

REGISTRATION NUMBER: _____ FILE NUMBER: _____

DATE ISSUES: _____ RECEIPT NUMBER: _____

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This form must be completed, notarized and accompany each application signed by the Designated Representative (DR).

AFFIDAVIT OF APPLICANT

WHOEVER KNOWINGLY AND WILLFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION MAY BE PROSECUTED UNDER APPLICABLE STATE LAWS. IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN DENIAL OR REVOCATION OF PERMIT.

I, the above-named applicant, state, under oath, that I am the person referred to in this questionnaire and that all the statements herein contained are each and all strictly true in every respect. I understand that false or forged statements made in connection with this questionnaire constitutes grounds for the Mississippi Board of Pharmacy to refuse to issue or renew, suspend, restrict, revoke or take other disciplinary action against my permit in the State of Mississippi. I understand that if I am issued a permit, failure to comply with the laws or regulations governing the distribution of drugs in this state, or any other state, will be cause for disciplinary action by the Mississippi Board of Pharmacy.

Further, that I give my consent for the release to the Mississippi Board of Pharmacy of any and all records or any other information which may relate to the above questions or my practice from any source or jurisdiction.

_____	_____	_____
Signature of Designated Representative	Printed Name	Date

Sworn to before me and subscribed in my presence this _____ day of _____, 20___

(seal)

Notary Public
My Commission Expires _____