



Alabama State Board of Pharmacy New Manufacturer Application

Date Received

Office Use Only

Manufacturer:

A person or entity, except a pharmacy, who prepares, derives, produces, researches, test, labels, or packages any drug medicine, chemical, or poison.

- Please be sure that you have reviewed the license type definitions and selected the proper new application.
- Application **must be signed by the owner, officer, or CEO only**. Power of Attorney's will not be accepted.
- Follow all directions completely as failure to submit required documentation will cause delays in processing your new application.
- You must submit all required documentation with the application packet. Forms will not be pulled from other applications. Incomplete submissions could result in withdrawal of your application. **Applications fees are non-refundable.**
- If additional forms are needed, please make copies. If additional space is required to answer a question, please attach the information on a separate sheet of paper.
- Section A is the **check list**. The documents listed are required for submission with the new application packet. All applicants must comply, or the application will be returned.
- Additional information may be requested through a deficiency email based on information provided on the application. This is part of our detailed comprehensive review process. The applicant will have **30 days from the date of the email** to comply to the deficiency email. If compliance is not met within 30 days, then the application will be considered abandoned and the application will be withdrawn, and no refunds will be issued. If the applicant complies the documents will be reviewed, then a permit will be issued, or another deficiency email will be issued for additional information. Again, this is part of our comprehensive review process. Multiple deficiency emails could be submitted during a review process. Due to the volume of applications received, weekly status reports will not be possible.
- Section B is **Ownership** and is based on the answer chosen in Section 6 of the application. For Example: If the selection is D, Corporation, then you would refer to Section B – F and provide the forms in Section D, for Corporation. Under each form are the instructions and additional information required to complete this section. This process is the same for section B – F. The applicant may print or copy The Individual History Affidavit Form and Business History Affidavit Form as many times as applicable.

Mail Completed Applications to:
Alabama Board of Pharmacy
111 Village Street
Birmingham, AL 35242

I. Check List (Section A) Required for All Applicants

All applicants **must** complete and submit the following documents:

- Completed New **Manufacturer Application**

- Proof of entity (foreign or domestic) registration with the Alabama Secretary of State.** www.sos.state.al.us

- Payment Form and check if applicable (Application fees are non-refundable)**
 - New Permit Fee \$750 Controlled Substance Permit Fee \$600.
 - *These are two separate fees, if you need a controlled substance permit the total cost will be \$1,350.00*

- DEA Certificate (copy) or Controlled Substance Waiver**
 - If you are applying for a controlled substance permit you will need to provide a copy of your DEA certificate.
 - All other applicants must complete the **Controlled Substance Waiver**.

- Facility Designated Representative** (Section 5 of application)
 - This must be a person of authority that works at the applicant facility.
 - An **Individual History Affidavit Form** must be completed for this person.

- Copy of Home State License**
 - This must be a copy of the actual certificate.
 - If your state does not require your facility to have a license, provide proof of exemption.

- Verification of the Home State License**
 - This can be a current online verification from the home state issuing agency, but the printed verification should be within the past 30 days.
 - Verifications mailed directly to our office from other regulatory agencies will not be accepted. The verification must be submitted with all other required documentation as part of the original submission.
 - If your state does not require your facility to have license, provide proof of exemption.

- Proof of registration with the Food and Drug Administration**
 - Drug Establishments Current Registration Site or Establishment Registration & Device Listing Site (this can be a printed screen shot of your listing)
 - If your facility is distribution only provide a list of the facilities that send their products to your location for distribution. The list needs to include their company name, address, and FDA FEIN.

- Application Contact Form**
 - One contact per new application only.

- Additional Information may be requested in the Application**
 - Read over the application carefully for any additional information that may be required.
 - Failure to provide the additional information will delay/prevent processing and the issuing of a permit.

II. Ownership: Section B-F is based on the answer chosen in Section 6 of the application.

(Section B) Individual Owner

Individual History Affidavit Forms

Complete one form for Owner(s) listed in section 6 of the application.

Business History Affidavit Forms

Complete one form for the Applicant Business.

(Section C) Partnership

Individual History Affidavit Forms

Complete one form for each Partner/Authorized Agent listed in section 6 of the application.

Business History Affidavit Forms

Complete one form for the Applicant Business and any Entity Owner listed in section 6 of the application.

Partnership Agreement

Current executed agreement

(Section D) Corporation

Individual History Affidavit Forms

Complete one form for each owner, officer, stockholder, and executive officer listed in section 6 of the application.

Business History Affidavit Forms

Complete one form for the Applicant Business and any Entity Owner listed in section 6 of the application.

Ownership Organizational Chart

Provide an organizational chart that clearly outlines the company's ownership structure and includes percentages for each party.

(Section E) Publicly Traded Corporation

Individual History Affidavit Forms

Complete one form for each executive officer and any authorized agent listed in section 6 of the application.

Business History Affidavit Forms

Complete one form for the Applicant Business and any Entity Owner listed in section 6 of the application.

(Section F) Limited Liability Company

Individual History Affidavit Forms

Complete one form for each member, executive officer, and authorized agent listed in section 6 of the application.

Business History Affidavit Forms

Complete one form for the Applicant Business and any Entity Owner listed in section 6 of the application.

Ownership Organizational Chart

Provide an organizational chart that clearly outlines the company's ownership structure and includes percentages for each party.



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1. Applicant Business Details

Name of Business:			
All other trade or business names ("DBA" names) used by applicant:			
Business Address: <i>Number and Street</i>			
<i>City</i>	<i>State</i>	<i>Zip</i>	<i>County (If in Alabama)</i>
Telephone Number for Business:		Federal Employer Identification Number/TIN:	
FDA Federal Establishment Identification Number:		<input type="checkbox"/> Distribution Only Facility –Attach a list with the name, address, and FEIN# for each establishment for whom you distribute products.	
What is the date of applicant's last FDA inspection? (Attach a copy)			
<input type="checkbox"/> Not applicable (If this facility is not required to be inspected by the FDA, please check the box)			

1. Hours of Operations

<i>Monday - Friday</i>	<i>Saturday</i>	<i>Sunday</i>
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2. Business Operations

2a. The Applicant Business will Ship to: (Mark all that apply) <input type="checkbox"/> Community pharmacies <input type="checkbox"/> Hospitals <input type="checkbox"/> Wholesale Distributors <input type="checkbox"/> Licensed Prescriber <input type="checkbox"/> Third Party Logistics Provider <input type="checkbox"/> Repackagers <input type="checkbox"/> Other: _____	2b. Type of product Manufactured: (Mark all that apply) <input type="checkbox"/> Controlled substances <input type="checkbox"/> Prescription drugs (human) <input type="checkbox"/> Precursor chemicals <input type="checkbox"/> Devices <input type="checkbox"/> Veterinary <input type="checkbox"/> API <input type="checkbox"/> Other: _____
2c. Do you currently have a federal registration with the Drug Enforcement Administration? <input type="checkbox"/> Yes DEA #: _____ Exp. Date: _____ <input type="checkbox"/> No - Please complete Controlled Substance Waiver Form found attached.	2d. Mark all schedules listed on your DEA registration: <input type="checkbox"/> Schedule II <input type="checkbox"/> Schedule III <input type="checkbox"/> Schedule IV <input type="checkbox"/> Schedule V

3. API/Product/Drug

Does applicant import bulk API?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does applicant import prescription-only drugs in final dosage form?	<input type="checkbox"/> Yes <input type="checkbox"/> No

3a. If you answered "yes" to either of the above questions attach a list with the name, address, and FDA FEIN# of all companies from which you purchase these items.

4. Discipline/Settlement/FDA 483/Warning

Has any final judgment been entered or settlement reached resulting from a claim or action for damages caused by any error, omission or negligence in the performance of any pharmacy or pharmaceutical professional services?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has this business ever surrendered, had suspended or lost its license or received any other disciplinary action?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Has the applicant ever received a FDA 483, warning letter, recall, or seizures?	<input type="checkbox"/> Yes <input type="checkbox"/> No

4a. If you answered "yes" to any of the above questions attach a copy of the official documents and an explanation to the application.

5. Facility Designated Representative: This must be a person of authority that work at the applicant's facility.

5a. In addition, an Individual History Affidavit Form must be completed for this person.

Name	Date of Birth	Social Security Number
Title	Email	
Phone Number	Home Address: <i>Number and Street</i>	
City	State	Zip

6. Ownership: Section B-F is based on the answer chosen in Section 6 of the application.

Ownership details must be provided for the applicant business. These details may include a parent company, and officers, partner, or members (as appropriate) for the business. (See section B – F)

Type of Ownership: <input type="checkbox"/> Individual Owner <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation (Not publicly traded) <input type="checkbox"/> Publicly Traded Corporation <input type="checkbox"/> Limited Liability Company
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6a. Entity Owners

If the applicant business is owned by an entity (not a natural person), the applicant must identify each parent company that has 10% or more ownership.

Name	FEIN/TIN#	% of Ownership	Phone Number
Address: <i>Number and Street</i>	<i>City</i>	<i>State</i>	<i>Zip</i>
Authorized Agent	Authorized Agent Phone Number:		

Name	FEIN/TIN#	% of Ownership	Phone Number
Address: <i>Number and Street</i>	<i>City</i>	<i>State</i>	<i>Zip</i>
Authorized Agent	Authorized Agent Phone Number:		

Name	FEIN/TIN#	% of Ownership	Phone Number
Address: <i>Number and Street</i>	<i>City</i>	<i>State</i>	<i>Zip</i>
Authorized Agent	Authorized Agent Phone Number:		

Name	Title	Date of Birth	Social Security Number
Address: <i>Number and Street</i>		<i>City</i>	<i>State</i> <i>Zip</i>
Phone Number	Email Address		

In signing, the MANUFACTURER applicant agrees to:

- Provide names of trading partners, suppliers and purchasers, when requested.
- Comply with federal and state regulations regarding import and export regulations.
- Assist and cooperate with state of Alabama inspections/investigations regarding operation of businesses and facility (s) covered by this application.

It is affirmed that all information provided herein is true and correct and it is recognized that providing false information may result in disciplinary action. It is understood that there must be compliance with the provisions of the Alabama Pharmacy Act, the Rules of the Board and all other applicable statutes and rules.

Signature Owner, Officer, or CEO only

Title

Printed Name

Date

Are you a US Citizen? YES NO If NO, Submit documentation of legal status in this country.

FORM MUST BE NOTARIZED

Subscribed and sworn to before me this _____ day of _____, 20_____ A.D.
APPLICATION MUST BE NOTARIZED

Notary Public (seal)



INDIVIDUAL HISTORY AFFIDAVIT FORM

Date Received
Office Use Only

Name: <i>First</i> <i>MI</i> <i>LAST</i>			Date of Birth:
Social Security Number:	Telephone Number:	Email Address:	
Home Address: <i>Number and Street</i>		<i>City</i>	<i>State</i> <i>Zip</i>

Company Name:	Permit Number:
Company Address: <i>Number and Street</i>	<i>City</i> <i>State</i> <i>Zip</i>

Position with Business: *(Check all that apply)*

Owner
 Partner
 Officer
 Stockholder
 Member
 Designated Representative

Other: Specify _____

Provide details for any professional or vocational license held in the past five years. (Pharmacist, physician, dentist, veterinarian attorney, accountant etc.)

License Held	State Issued	License Number

1.	Have you ever been an owner, partner, officer, or member of any business (partnerships, corporation, firm, or association) whose license was denied, revoked, suspended, surrendered or placed on probation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Have you ever had any professional or vocational (e.g. pharmacist, technician, pharmacy) license/registration revoked, suspended, denied, suspended, placed on probation or any other disciplinary action by any Federal or State authority?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Have you ever been arrested and/or convicted of a felony or misdemeanor (excluding minor traffic violations that do not involve drugs or alcohol) in any state?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Has any final judgment been entered or settlement reached resulting from a claim or action for damages caused by any error, omission or negligence in the performance of any pharmacy or pharmaceutical professional services?	<input type="checkbox"/> Yes <input type="checkbox"/> No

If you answered "Yes" to any of the above questions you must attach an explanation that includes the date, license type, license number, your position, state issued, and a copy of any arrest records, board orders, or court proceedings.

It is affirmed that all information provided herein is true and correct and it is recognized that providing false information may result in disciplinary action. It is understood that there must be compliance with the provisions of the Alabama Pharmacy Act, the Rules of the Board and all other applicable statutes and rules.

Signature

Title

Printed Name

Date

FORM MUST BE NOTARIZED

Subscribed and sworn to before me this _____ day of _____, 20____ A.D.

APPLICATION MUST BE NOTARIZED _____
Notary Public (seal)



NEW BUSINESS HISTORY AFFIDAVIT FORM

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Permit Holder (Business) Name:	Permit Number:
Company Address: <i>Number and Street</i>	<i>City</i> <i>State</i> <i>Zip</i>

Name of Entity Owner:	FEIN/TIN#
Address: <i>Number and Street</i>	<i>City</i> <i>State</i> <i>Zip</i>
Name of Authorized Agent:	Phone Number:
Authorized Agent's Position: <input type="checkbox"/> Owner <input type="checkbox"/> Member <input type="checkbox"/> Manager <input type="checkbox"/> Principal <input type="checkbox"/> Executive Director	

1.	Has this business ever been an owner, partner, officer, or member of any business (partnerships, corporation, firm, or association) whose license was denied, revoked, suspended, surrendered or placed on probation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Has this business ever been in violation of any part of the Alabama Pharmacy Law or its regulations?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Has this business ever been charged and/or convicted of violating any Federal or U.S. State law?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Has any final judgment been entered or settlement reached resulting from a claim or action for damages caused by any error, omission or negligence in the performance of any pharmacy or pharmaceutical professional services?	<input type="checkbox"/> Yes <input type="checkbox"/> No

If you answered Yes to any of the above questions you must attach an explanation that includes the date, license type, license number, your position, state issued, and a copy of any arrest records, disciplinary orders, or court proceedings.

It is affirmed that all information provided herein is true and correct and it is recognized that providing false information may result in disciplinary action. It is understood that there must be compliance with the provisions of the Alabama Pharmacy Act, the Rules of the Board and all other applicable statutes and rules.

Signature Owner, Officer, or CEO only

Title

Printed Name

Date

FORM MUST BE NOTARIZED

Subscribed and sworn to before me this _____ day of _____, 20____ A.D.
APPLICATION MUST BE NOTARIZED

Notary Public (seal)



CONTROLLED SUBSTANCE WAIVER

Date Received
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Applicant Business Information

Name of Business:			
Address of Business: Number and Street	City	State	Zip Code

I am hereby requesting the Board to issue only a permit and that no activities requiring a controlled substance registration will be performed during the referenced period. I understand that providing a false statement or engaging in any activity requiring a controlled substance registration may result in discipline.

Signature Owner, Officer, or CEO only

Title

Printed Name

Date

FORM MUST BE NOTARIZED

Subscribed and sworn to before me this _____ day of _____, 20_____ A.D.
APPLICATION MUST BE NOTARIZED

Notary Public (seal)



Application Contact Person

Date Received
Office Use Only

Applicant Business Information

<i>Name of Business:</i>			
<i>Address of Business: Number and Street</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>

Please provide the best contact details for the person to be contacted regarding any deficiencies, questions, or concerns regarding this application. All official correspondence regarding this application will be directed to this individual only.

<i>Name:</i>	<i>Telephone Number:</i>		
<i>Mailing Address: Number and Street</i>	<i>City</i>	<i>State</i>	<i>Zip Code</i>
<i>Email Address:</i>			

Signature Owner, Officer, or CEO only

Title

Printed Name

Date



PAYMENT FORM

Date Received
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You may pay by check or credit card. Please denote below which method of payment you will be sending.

Business Name: _____ Permit # _____

Check # _____ is attached – Please make check payable to the Alabama State Board of Pharmacy

Charge fees to credit card (There will be an additional 5% transaction fee)

Credit Card Type: Visa MasterCard Discover American Express (please circle)

Card Number: _____

Expiration Mo/Yr: _____ / _____ (MM/YY)

Security Code _____

Card Holder Name: _____

Complete Billing Address: _____

(City) (State) (Zip)

Signature of Card Holder _____

MUST be Signature of Card Holder

If you need a transaction receipt, please provide an email address.
