



## Alabama State Board of Pharmacy New Drug Manufacturer Application

Date Received

Office Use Only

### Drug Manufacturer:

Every facility, except a pharmacy, that prepares, derives, produces, compounds, or packages any drug, chemical, or poison.

- Follow all instructions and include all required supporting documents on the checklist. The application and all supporting documents **must be submitted as one complete submission.**
- Only completed applications will be accepted. **Application fees are non-refundable.**
- An application **must be signed by the owner, officer, or CEO only.** Power of Attorney's are not accepted.
- **All signatures must be less than 90 days old at the time of receipt.**
- **Print single sided pages only. No double-sided applications will be accepted.**
- All required forms must be provided for each submission. Documents will not be pulled from other applications.
- Please use a jump drive for "any/all attachments" over 10 pages.
- Do not staple pages. Paper clips and binder clips are acceptable.
- No copies will be accepted. Original "wet" signatures are required.
- No digital signatures will be accepted.
- Please **use the space provided** on the applications. 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 **once all space is used** on the application.
- If you have additional questions regarding the application process, please review the ***Facility Application FAQ's*** on our website <https://www.albop.com>.

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

## I. Check List

All applicants must complete and submit the following documents:

- ☐ **Completed New Drug Manufacturer Application**
- ☐ **Check made payable to: Alabama State Board of Pharmacy (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*
- ☐ **Proof of entity (foreign or domestic) registration with the Alabama Secretary of State. [www.sos.state.al.us](http://www.sos.state.al.us)**
- ☐ **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**
  - This person must be registered with the Alabama State Board of Pharmacy. Please visit our website to begin the required registration at [www.albop.com](http://www.albop.com) prior to submitting your application if you have not already registered. \*\*This process does not need to be completed prior to submitting your application, but your designated representative must be registered for a permit to be issued. \*\*
  - This requirement MUST be met prior to your permit being approved by our office.
  - See a full list of requirements under Alabama Administrative Code **680-x-2-.23 (9)**.
- ☐ **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.
  - 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 MUST include the company name, address, active Alabama permit number, and FDA EIN. If this information is missing, your application will not be accepted.
- ☐ **Description of Operations**
  - A written description of all services/operations provided at this facility.
- ☐ **Ownership Organizational Chart**
  - The Chart must show the legal business entities from the ultimate parent company down to and including the applicant and must include the legal business name, trade name, tax identification (if US company) and type (parent/grandparent) of ownership for each entity on the chart as well as percentages owned. Individual Ownership Organizational Chart must include the Owners name, title and percentage owned on the chart.
- ☐ **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:

### Individual Owner

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☐ **Individual History Affidavit Forms**

Complete one form for Owner listed in section 3 of the application.

☐ **Business History Affidavit Forms**

Complete one form for the Applicant Business.

### Partnership

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☐ **Individual History Affidavit Forms**

Complete one form for each Partner listed in section 3 of the application.

☐ **Business History Affidavit Forms**

Complete one form for the Applicant Business.

### Corporation

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☐ **Individual History Affidavit Forms**

Complete one form for each owner, officer, stockholder, and executive officer listed in section 3 of the application.

☐ **Business History Affidavit Forms**

Complete one form for the Applicant Business and any Entity Owner listed in section 3 of the application.

### Publicly Traded Corporation

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☐ **Individual History Affidavit Forms**

Complete one form for each executive officer listed in section 3 of the application.

☐ **Business History Affidavit Forms**

Complete one form for the Applicant Business and any Entity Owner listed in section 3 of the application.

### Limited Liability Company

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☐ **Individual History Affidavit Forms**

Complete one form for each member, manager, executive officer, or any person listed in section 3 of the application.

☐ **Business History Affidavit Forms**

Complete one form for the Applicant Business and any Entity Owner listed in section 3 of the application.

**\*\*\*Additional information could be requested/required throughout the application process\*\*\***



# Alabama State Board of Pharmacy New Drug Manufacturer Application

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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>			
City	State	Zip	County (If in Alabama)
Telephone Number for Business:		Federal Employer Identification Number/TIN:	

## Hours of Operations

Monday – Friday	Saturday	Sunday
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## 2. Facility Designated Representative: (requirements are listed on the checklist)

Name	Current Alabama Registration Number ****REQUIRED prior to permitting****
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## 3. Ownership: Ownership details must be provided for the applicant business. Include the details for the parent level ownership.

### 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

## Entity Owners

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

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

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

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

### **Natural Person Ownership**

Complete the details below for each owner, partner, member and/or stockholder (as appropriate) with 10% or more ownership that is a natural person owner for this business.

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

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

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

### **Executive Officer(s):**

Complete the details for each executive officer for the business. At a minimum you must include the top 3 officers. **\*Do not Leave Blank\***

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

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

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

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

**In signing, the DRUG 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 of 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)



## Drug Manufacturer Operational Information

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1. FDA Establishment Identification Number \_\_\_\_\_

☐ Not Applicable Distribution Facility Only\*

***\*Must attach a list with the name, address, and FDA Establishment Identification Number of the facilities that physically manufactures the product distributed from applicant facility. If this is not provided, your app will not be accepted.***

2. FDA Labeler Code Number \_\_\_\_\_

3. Date of last FDA Inspection\* \_\_\_\_\_

***\*Attach an unredacted copy of the inspection, and unredacted response if applicable.***

4. Does the applicant facility hold NABP Drug Distributor Accreditation (f/k/a VAWD)? ☐ Yes ☐ No

Has the facility had an NABP Supply Chain Inspection? ☐ Yes\* Date \_\_\_\_\_ ☐ No

***\*Attach a complete unredacted copy of the inspection***

5. The applicant business will ship/sell product to:

☐ Community pharmacies ☐ Hospitals ☐ Wholesale Distributors ☐ Licensed Prescriber ☐ Third-Party Logistics Providers  
☐ Repackagers ☐ Other: \_\_\_\_\_

6. Type of product Manufactured:

☐ Prescription drugs (human) ☐ Precursor Chemicals ☐ Prescription Devices ☐ Prescription Drugs (veterinary) ☐ API  
☐ Other: \_\_\_\_\_

7. Do you intend to ship/sell Federally controlled substances?

☐ Yes DEA Number \_\_\_\_\_ Expiration \_\_\_\_\_  
☐ No

8. Do you intend to ship/sell Alabama specific controlled substances? ☐ Yes ☐ No

***\*If you answered "No" to questions 6 & 7 you must complete a controlled substance waiver.***

9. Does the applicant import bulk API? ☐ Yes\* ☐ No

Does the applicant import prescription-only drugs in final dosage form? ☐ Yes\* ☐ No

***\*Attach a list with the name, address, and FDA EIN# of all companies from which you purchase these items.***



## Application Contact Person

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### Applicant Business Information

Name of Business:

Address of Business: Number and Street

City

State

Zip Code

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

Name:

Telephone Number:

Company Name:

Business Mailing Address: Number and Street

City

State

Zip Code

Email Address:

Signature Owner, Officer, or CEO only

Title

Printed Name

Date

We recommend adding [sgamble@albop.com](mailto:sgamble@albop.com) to your email contact list to help prevent missing important correspondences.





# INDIVIDUAL HISTORY AFFIDAVIT FORM

Date Received

Office Use Only

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

Position with Business: (Check all that apply)

☐ Owner ☐ Partner ☐ Officer ☐ Stockholder ☐ Member

☐ Other: Specify \_\_\_\_\_

1.	Have you been arrested?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Have you been convicted of a felony or misdemeanor, excluding minor traffic conviction?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Have you been convicted of violating any laws regulating controlled substances or prescription legend drugs?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Have you ever been issued a license to practice pharmacy or as a pharmacy technician?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Has any license, permit, registration, certification or like authority issued to you or any entity you own/owned in whole or part by any board of pharmacy or any other occupational or regulatory board been sanctioned or subject to discipline in any way? If so, attach a copy of the discipline.	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Are you currently or have you ever been charged with a substance abuse violation or been in a substance abuse treatment program?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	Are there currently any pending investigations or charges regarding any license, permit or registration issued to you?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Have you ever been denied, refused, or withdrawn an application for a permit or surrendered a license once issued for a pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B outsourcer and/or third-party logistics company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Have you or any entity you own/owned in whole, or part ever surrendered or failed to renew any license, permit, registrations, certification or like authority issued by any board of pharmacy or any other regulatory board? If so, list state, type of license, etc., the occupation or profession, and reason for the surrender or failure to renew.	<input type="checkbox"/> Yes <input type="checkbox"/> No
10.	Have you or any entity you own/owned in whole or in part ever been denied any license, permit, registration, certification or like authority by any board of pharmacy or any other occupational or regulatory board? If so, list state, type of license, etc., the occupation or profession, and reason for denial.	<input type="checkbox"/> Yes <input type="checkbox"/> No
11.	Have you been licensed, permitted, or registered in any other state(s) as a pharmacist, pharmacy technician or any other position requiring a license, permit or registration from a pharmacy board or requiring a permit involving dispensing controlled substances?	<input type="checkbox"/> Yes <input type="checkbox"/> No
12.	Has an FDA 483 or Warning Letter ever been issued to any entity in which you have been or are currently involved/affiliated?	<input type="checkbox"/> Yes <input type="checkbox"/> No
13.	Has any final judgement 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 by the Applicant or any Owner, Officer, Member, Director, or Partner or by you?	<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, disciplines, 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)

01/2024





## CONTROLLED SUBSTANCE WAIVER

Date Received

Office Use Only

### 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)