



Alabama State Board of Pharmacy New Private Label Distributor Application

Date Received

Office Use Only

Private Label Distributor:

A firm that does not participate in the manufacturing or processing of a drug but instead markets and distributes under its own trade name and labels a drug product made by someone else. A private label distributor is responsible for the products it introduces into interstate commerce and for compliance with federal Food, Drug, and Cosmetic Act requirements and Current Good Manufacturing Practices regulations.

- Please be sure that you have reviewed the license type definitions and selected the proper new application.
- 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**. **Application fees are non-refundable**.
- An application **must be signed by the owner, officer, or CEO only**. Power of Attorney's will not be accepted. **All signatures must be less than 90 days old at time of submission**.
- 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.
- 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.
- 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 Private Label Distributor 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**
- 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**
 - See a full list of requirements under Alabama Administrative Code 680-x-2-.23(h).
 - This person must be a U.S. Citizen or legally present in the United States with appropriate documentation for the Federal Government.
 - 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.
- Labeler Code(s), NDC Number(s)**
 - Provide a list of all Drugs and/or Devices listed under this number(s)
 - If you currently do not report any drugs/devices to the FDA National Drug Code Directory, please explain why and provide details that include when your product(s) is expected to launch or be approved.
- Contract Manufacturer and/or Third-Party Logistics providers contracts**
 - Copy of the first page and signature page of contracts with your contract manufacturer(s) and third-party logistics provider(s).
- Description of Operations**
 - A written description of all services provided at this facility.
- Ownership Organizational Chart**
 - 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 of ownership for each entity on the chart. Chart must include all owner's name with a 10% or greater ownership interest in a non-publicly traded company.
- Application Contact Form**
 - One contact per new application only.

II. Ownership:

Individual Owner

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

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

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

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

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.



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New Private Label Distributor
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		Date of Birth	Social Security Number
Title		Email	
Phone Number		Home Address: <i>Number and Street</i>	
City	State	Zip	Are you a U.S. Citizen? <input type="checkbox"/> Yes <input type="checkbox"/> No

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
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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.

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:	

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:	

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.

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	% of Ownership	

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	% of Ownership	

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	% of Ownership	

Executive Officer(s):

Complete the details for each executive officer for the business. At a minimum you must include the top 3 officers

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		

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		

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 PRIVATE LABEL DISTRIBUTOR 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)



Private Label Distributor Operational Information

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1. FDA Labeler Code Number _____
2. 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*
3. The applicant business will ship/sell product to:
 Community pharmacies Hospitals Wholesale Distributors Licensed Prescriber Third-Party Logistics Providers
 Repackagers Other: _____
4. Type of product Distributed:
 Prescription drugs (human) Precursor Chemicals Prescription Devices Prescription Drugs (veterinary) API
 Other: _____
5. Do you intend to ship/sell Federally controlled substances?
 Yes DEA Number _____ Expiration _____
 No
6. Do you intend to ship/sell Alabama specific controlled substances? Yes No
**If you answered "No" to questions 5 & 6 you must complete a controlled substance waiver.*
7. Does this facility take physical possession of product (drugs/devices) at any time? Yes No

Contract Third Party Logistics Provider Details Not Applicable

Please list additional Third-Party Logistics Providers on a separate page with all requested details.

Name	Alabama Permit #
Address	

Name	Alabama Permit #
Address	

Contract Manufacture Details

Please list additional manufactures on a separate page with all requested details.

Name	FDA EIN
Address	

Name	FDA EIN
Address	



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)



NEW BUSINESS HISTORY AFFIDAVIT FORM

Date Received
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[] Applicant Business [] Business Entity Owner

Name: FEIN/TIN#
Address: Number and Street City State Zip

Table with 7 rows of questions regarding arrests, pharmacy licenses, and FDA issues. Each row includes a question and 'Yes/No' checkboxes.

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)
8/20



INDIVIDUAL HISTORY AFFIDAVIT FORM

Date Received
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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
 Designated Representative

Other: Specify _____

1.	Have you been arrested and/or convicted of a felony or misdemeanor, excluding minor traffic convictions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Have you ever had any action against your personal professional or vocational license (Pharmacist, Physician, Dentist, etc) that resulted in any disciplinary action such as suspension, probation, or revocation?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Have you ever owned or now own in whole or part any pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B Outsourcer, and/or third-party logistics company? If so, has any license or permit issued to any described entity been surrendered or subject to discipline in connection with the activities of any such entity or charged and/or convicted of any felony or misdemeanor excluding minor traffic violations?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Have you ever been denied or refused an application for a permit 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
5.	Have you ever withdrawn an application for a permit or surrendered license once issued to any pharmacy, manufacturer, wholesaler, distributor, repackager, private label distributor, 503B Outsourcer, and/or third-party logistics company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Have you ever owned in whole or in part or now own any entity that has been denied, refused or withdrawn an application for a permit or license of a pharmacy, manufacturer, wholesale distributor, repackager, private label distributor, 503B Outsourcer and/or third-party logistics company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	Have you ever been issued a license to practice pharmacy or as a pharmacy technician?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	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
9.	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 you or any entity that you have been an Owner, Officer, Member, Director, or Partner thereof?	<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)



Application Contact Person

Date Received
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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 kpickett@albop.com and sgamble@albop.com to your email contact list to help prevent missing important correspondence.