



# Alabama State Board of Pharmacy New 503B Outsourcing Application

Date Received

Office Use Only

## 503B Outsourcing:

A facility at one geographic location or address that is engaged in the compounding of sterile drugs, which has elected to register with the federal Food and Drug Administration as an outsourcing facility and complies with the requirements of Section 503B(d)(4)(A) of the federal Food, Drug, and Cosmetic Act.

- 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 503B Outsourcing 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 DEACertificate.
  - All other applicants must complete the **Controlled Substance Waiver**.
- Alabama Supervising Pharmacist 680-x-2-.23(h)
  - Please refer to for full requirements Alabama Administrative Code 680-x-2.12
  - 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 as an FDA Registered Outsourcing Facility
  - This can be a printed screen shot of your registration.
- 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.
- List of all compounds made at the applicant facility
- Copy of your beyond use date policy
- List of all chemicals that you use that appear on the NIOSH list
- Copy of your policy on testing compounds (potency, stability, sterility, and endotoxins)
- A labeled floor plan of your facility
- Copy of your most recent environmental test/certifications
- Pictures of the applicant facility (ex: clean room, hoods, bio safety cabinet, etc.)
- Unredacted copy of any/all FDA 483's, warning letters, and applicant's response to each
- Copy of any/all discipline, recalls, and seizures

## 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.



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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:	

## Hours of Operations

<i>Monday – Friday</i>	<i>Saturday</i>	<i>Sunday</i>
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## 2. Alabama Supervising Pharmacist:

Name:	Alabama License#:
Email:	

## 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
<b>Address:</b> <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>	

<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.

<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 503B Outsourcer 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)



# 503B Outsourcing Operational Information

Date Received
Office Use Only

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

2. FDA Labeler code# \_\_\_\_\_

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

**\*Attach an unredacted copy**

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

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

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

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

5. 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.**

6. Does the applicant use bulk API for compounding?  Yes\*  No

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

7. Do you fill any orders pursuant to a prescription:  Yes  No







# 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)



# 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>

**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)



# NEW BUSINESS HISTORY AFFIDAVIT FORM

Date Received
Office Use Only

Applicant Business     Business Entity Owner

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

1.	Has this entity or any Owner, Officer, Member, Director, Manager or Partner thereof been arrested and/or convicted of a felony or misdemeanor, excluding minor traffic convictions?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Has this entity ever owned or now own in whole or part any pharmacy, manufacturer, wholesale 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 that do not include drugs or alcohol)?	<input type="checkbox"/> Yes <input type="checkbox"/> No  <input type="checkbox"/> Yes <input type="checkbox"/> No
3.	Has this entity ever been denied or refused an application for a permit for a pharmacy, manufacturer, wholesale distributor, repackager, private label distributor, 503 outsourcer and/or third-party logistics company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Has this entity ever withdrawn an application for a permit or surrendered a license once issued to any pharmacy, manufacturer, wholesale distributor, repackager, private label distributor, 503B outsourcer, and/or third-party logistics company?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Has this entity 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
6.	Has an FDA 483 or Warning Letter ever been issued to Applicant or to any entity in which any Owner, Officer, Member, Director, Manager, or Partner of the Applicant has been or is currently involved/affiliated?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	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, Manager or Partner?	<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)  
8/20



# Application Contact Person

Date Received
Office Use Only

## 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](mailto:kpickett@albop.com) and [sgamble@albop.com](mailto:sgamble@albop.com) to your email contact list to help prevent missing important correspondence.