



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.

- 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 will not be accepted.
- **All signatures must be less than 90 days old at the time of receipt.**
- All 503B Outsourcing Applicants must provide an unredacted copy of your most recent **"Working FDA Inspection"**
- 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.
- 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 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
- 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**.
- 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.
 - 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. Individual Ownership Organizational Ownership Chart must include the Owners Name, Title and percentage owned on the chart.
- Application Contact Form
 - One contact per new application only.

****Please label and provide the following****

- 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.)
- Proof of most recent working FDA Inspection for Applicant and 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

- 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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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> |
|------------------------|-----------------|---------------|

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 |
|--|

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: | |

| | | | |
|--|------------------|---|-------------------------|
| 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. ***Do not leave blank***

| | | | |
|--|----------------------|----------------------|-------------------------------|
| 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 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 |
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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 |
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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> |

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? | <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)



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? | <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 any license or permit issued to any pharmacy, manufacturer, wholesale distributor, repackager, private label distributor, 503B Outsourcer, third-party logistics company and/or any other entity and/or any owner, officer, etc. thereof, been the subject of discipline by any pharmacy board or by any regulatory board from whom a license or permit has been issued? | |
| 5. | 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 |
| 6. | 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 |
| 7. | 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 |
| 8. | 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)
8/22



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