

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane – Reno, NV 89509 – (775) 850-1440
APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy
(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

- New Outsourcing Facility
 Ownership Change (Provide current license number if making changes:) OUT _____
 503a OR 503b Apply as retail pharmacy only.
- Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Publicly Corporation or Partnership
- | | |
|---|--|
| <input type="checkbox"/> Publicly Traded Corporation – Pages 1-3 & 4 | <input type="checkbox"/> Partnership - Pages 1-3 & 6 |
| <input checked="" type="checkbox"/> Non Publicly Traded Corporation – Pages 1-3 & 5 | <input type="checkbox"/> Sole Owner – Pages 1-3 & 7 |

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Cantrell Drug Company

Physical Address: 7321 Cantrell Road

City: Little Rock State: Arkansas Zip Code: 72207

Telephone: 501-663-3642 Fax: 501-296-9936

Toll Free Number: 877-666-5222 (Required per NAC 639.708)

E-mail: kallen@cantrelldrug.com Website: www.cantrelldrug.com

Supervising Pharmacist: Ashley D. Wagner Nevada License #: 19708

SERVICES PROVIDED

Yes/No

- | | | |
|-------------------------------------|-------------------------------------|----------------------------------|
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Parenteral |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Sterile Compounding |
| <input checked="" type="checkbox"/> | <input type="checkbox"/> | Non Sterile Compounding |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Mail Service Sterile Compounding |
| <input type="checkbox"/> | <input checked="" type="checkbox"/> | Other Services: _____ |

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: _____ Amount: \$ 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

FEI Number (From FDA application): 71-0555575

Please provide the name of the facility as registered with the FDA and the registration number:
Cantrell Drug Company - 3004483441

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
N/A

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Ashley DeAnn Wagner Nevada License Number: 19708

A Nevada business license is not required, however if the Outsourcing Facility has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes No
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes No
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes No
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes No
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes No

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION

State of Incorporation: Arkansas
 Parent Company if any: Cantrell Drug Company
 Address: 7321 Cantrell Road
 City: Little Rock State: AR Zip: 72207
 Telephone: 501-663-3642 Fax: 501-296-9936
 Contact Person: Kayla Allen

For any corporation non publicly traded, disclose the following:

- 1) List top 4 persons to whom the shares were issued by the corporation?

a)	<u>James L. McCarley, Jr.</u>	<u>#2 Calle Nairn, Condo #1001, San Juan, PR 00907</u>
	Name	Address
b)	<u>Lynn H. McCarley</u>	<u>#2 Calle Nairn, Condo #1001, San Juan, PR 00907</u>
	Name	Address
c)	<u>N/A</u>	
	Name	Address
d)	<u>N/A</u>	
	Name	Address
- 2) Provide the number of shares issued by the corporation. 200
- 3) What was the price paid per share? \$1
- 4) What date did the corporation actually receive the cash assets? 01-31-1992
- 5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

* see attached



CANTRELL DRUG COMPANY

Pharmaceutical Outsourcing Specialists

Nevada State Board of Pharmacy
431 W. Plumb Lane
Reno, Nevada 89509

Ladies and Gentlemen:

In reference to question #2, Georgia Board of Pharmacy denied our application for a Manufacturer license. We will provide additional documentation to Georgia Board of Pharmacy. We are currently licensed in Georgia as a Wholesaler Pharmacy. See attached letter from Georgia Board of Pharmacy.

In reference to question #3, after an FDA Inspection of our Outsourcing Facility and our remediation of all the observations of the FDA, the Boards of Pharmacy in South Carolina, Alabama, and Illinois asked for additional information and suspended our right to ship into those States until they are satisfied. Upon receiving our newly acquired Verified-Accredited Wholesale Distributors certification, Illinois has reinstated our right to ship. The South Carolina and Alabama Boards of Pharmacy have now held hearings. Following the hearing in South Carolina, its Board concluded that Cantrell Drug Company will be placed on a two year probationary period. Following the hearing in Alabama, its Board concluded that there had been a deficiency in sterile compounding and imposed a fine. See attached final orders from Alabama Board of Pharmacy and South Carolina Board of Pharmacy.

The Boards of Pharmacy in Colorado, Florida, Indiana, Missouri, and Minnesota have investigated the same facts surrounding this FDA Inspection and allowed us to continue shipping. In Florida, we have voluntarily agreed to restrict our practice in the state until we have a new Florida-approved inspection of our facility.

Also in reference to question #3, James L. McCarley was disciplined by the Kentucky Board of Pharmacy due to a miscalculation in completing continuing education credits which has now been rectified.

In reference to question #4, in 2003, the Drug Enforcement Administration investigated Cantrell Drug Company for an alleged violation of Title 21 USC in regard to compounded intrathecal pump refills sent to the ordering physician for administration by the physician. This practice is standard in most compounding pharmacies dispensing intrathecal medication refills in the United States. A settlement was reached in 2004 upon the terms set forth in a written agreement, a copy of which is attached. Furthermore, Cantrell Drug Company complied with DEA request to register the pharmacy as a "manufacturer" with the agency.

Let me know if you need further information.

Dell McCarley, Pharm D
CEO



Frank Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-651-8000 | www.dch.georgia.gov

September 26, 2017

Cantrell Drug Company
7321 Cantrell Road
Little Rock AR 72207

Application # 1885579
Email: kallen@cantrelldrug.com

Re: Manufacturing Pharmacy Application

Dear Cantrell Drug Company:

The Georgia Board of Pharmacy reviewed your application for licensure at its recent meeting. After careful consideration of your application and supporting documents, the Board respectfully disapproved your application for licensure for the following reason(s):

- Series of disciplinary action(s) and recall of sterile drug products; have not shown you meet the inspection standard of a 503B outsourcing facility.

Please be advised that you do have the right to an appearance before the Board to discuss your application. A written request for such must be put in writing within 30 days of the date of this letter. The request may be faxed to 770-344-5727 or emailed to bhowell@dch.ga.gov.

If our office can be of further assistance, please do not hesitate to contact us.

Sincerely,

Georgia Board of Pharmacy

ALABAMA
BOARD OF PHARMACY

SUSAN ALVERSON R.Ph.
Executive Secretary

Location:
111 Village Street
Birmingham, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com



MEMBERS 2017

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Brenda Denson, PharmD.

May 4, 2017

CANTRELL DRUG COMPANY
7321 CANTRELL RD
LITTLE ROCK AR 72207

RE: Final order

Dear Cantrell Drug Company:

Enclosed you will find a FINAL ORDER resulting from your hearing before the Board. While the entire order is important, I particularly direct your attention to the portion of the Order setting forth discipline and specifically the mandatory obligation of your payment of a fine and costs. As you will see, those amounts are due within a specified period of time from the date of the Final Order and not the date of this letter.

If the referenced fine and costs are not received by the Board within the prescribed period of time, or special arrangements have not been made with the Secretary of the Board, the Board will file a lawsuit to enforce the Final Order which can result in the entry of a judgment against you and subsequent collection procedures.

Sincerely,

Wendy Passmore

Legal / Executive Assistant
Alabama State Board of Pharmacy
Phone 205-981-4764
Fax 205-803-6481
Email - wpassmore@albop.com

IN THE MATTER OF:) BEFORE THE ALABAMA STATE
CANTRELL DRUG COMPANY) BOARD OF PHARMACY
Manufacturer/Wholesaler)
Distributor Permit Number 194828) Case Number 16-0168

FINAL ORDER

On April 18, 2017, this cause came before the Alabama State Board of Pharmacy (hereinafter also referred to as the "Board"), on a Complaint against Cantrell Drug Company (hereinafter also referred to as the "Respondent"). Evidence having been adduced thereon, the Board has determined that the following Stipulation and Agreement, Findings of Fact and Conclusions of Law are supported by the preponderant weight of evidence and law.

Stipulation and Agreement

Pursuant to Code of Alabama 1975, § 41-22-12 (f), the Respondent denies the allegations of the Statement of Charges, as Amended but stipulated that the Board could introduce sufficient evidence to establish a prima facie case necessary to meet the legal burden of proof as required by the Board for this proceeding. Therefore the Board finds the Respondent is guilty of committing the acts and violating the provisions of law set forth in the Statement of Charges, as Amended. The parties further agreed to the terms listed below in this Final Order.

Findings of Fact

1. The Respondent is a manufacturer/wholesaler/distributor to which the Board issued permit number 194828.
2. The Respondent was notified of the charges; the Respondent was represented at the administrative hearing by counsel, Mr. Michael W. Whisonant, Jr., Esq. and Mr. H. Hube Dodd, Esq. Mr. Dell McCarley, the Respondent's representative, also attended the hearing.

3. The Respondent made no objection to the timeliness of the Notice of Hearing.

4. The Respondent committed and is guilty of the acts specified as violations in the Statement of Charges and Notice of Hearing dated December 28, 2016 as Amended on March 23, 2017.

Conclusions of Law

1. The Alabama State Board of Pharmacy has jurisdiction in this cause pursuant to Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92 (11) and (12) and Code of Alabama (1975), § 41-22-12.

2. The Respondent was properly notified of the charges; the Respondent was represented at the administrative hearing by counsel.

3. The Respondent made no objection to the timeliness of the Notice of Hearing.

4. The Respondent's permit as a manufacturer/wholesaler/distributor in the State of Alabama is due to be have disciplinary sanctions imposed in that it is guilty of the acts specified in Count One of the Statement of Charges and Notice of Hearing dated December 28, 2016 and as Amended on March 23, 2017.

ORDER

In accordance with the foregoing Stipulation and Agreement, Findings of Fact and Conclusions of Law, it is hereby ORDERED as follows:

1. The Respondent is ORDERED to pay to the Board an administrative fine of Thirty Thousand (\$30,000.00) Dollars; said fine shall be paid in sixty (60) days from the date of this Final Order; and