# 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.

| XNew Outsourcing Facility<br>□Ownership Change (Provide current license number if making changes:) OUT<br>□ 503a OR X 503b Apply as retail pharmacy only.   |   |  |  |  |  |  |
|---|---|--|--|--|--|--|
| Check <u>box</u> below for type of ownership and complete all required forms for type of ownership that<br>you have selected. If LLC use Non Publicly Corporation or Partnership<br>□ Publicly Traded Corporation – Pages 1-3 & 4 □ Partnership - Pages 1-3 & 6<br>X Non Publicly Traded Corporation – Pages 1-3 & 5 □ 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   | 7 |  |  |  |  |  |
| Telephone: 501-663-3642 Fax: 501-296-9936   |   |  |  |  |  |  |
| Toll Free Number: 877-666-5222 (Required per NAC 639.708)   | 5 |  |  |  |  |  |
|   |   |  |  |  |  |  |
| E-mail: kallen@cantrelldrug.com Website: www.cantrelldrug.com   |   |  |  |  |  |  |
| Supervising Pharmacist: Ashley D. Wagner Nevada License #: 19708  |   |  |  |  |  |  |
| SERVICES PROVIDED   |   |  |  |  |  |  |
| Yes/No  |   |  |  |  |  |  |
| X D Parenteral  |   |  |  |  |  |  |
| X □ Sterile Compounding   |   |  |  |  |  |  |
| X □ Non Sterile Compounding   |   |  |  |  |  |  |
| Mail Service Sterile Compounding  |   |  |  |  |  |  |
| 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.  |   |  |  |  |  |  |
| Amount: \$ 500,00   |   |  |  |  |  |  |
| Board Use Only Date Processed: Amount:  |   |  |  |  |  |  |

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## 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: <u>Ashley DeAnn Wagner</u> Nevada License Number: <u>19708</u>

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<br>any interest, ever been charged, or convicted of a felony or gross<br>misdemeanor (including by way of a guilty plea or no contest plea)?              | Yes |   | No | X |
|----|--|-----|---|----|---|
| 2) | Has the corporation, any owner(s), shareholder(s) or partner(s) with<br>any interest, ever been denied a license, permit or certificate of<br>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 | X | 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 | X | 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.

## APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized Outsourcing Facility may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes 🗆 No 🖾

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.

Original Signature of Person Authorized to Submit Application, no copies or stamps

CEO ARLEY DR

Print Name of Authorized Person

# APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

## **OWNERSHIP IS A NON PUBLICLY TRADED CORPORATION**

| State of Incorporation:     | Arkansas              |     |
|-----------------------------|-----------------------|-----|
| Parent Company if any:      | Cantrell Drug Company | 8.3 |
| Address:7321 Cantrel        | Road                  | 12  |
| City: Little Rock           | State: AR Zip: 72207  |     |
| Telephone: <u>501-663-3</u> | 542 Fax: 501-296-9936 |     |
| Contact Person: Kayl        | a Allen               |     |

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For any corporation non publicly traded, disclose the following:

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

|  | a)_ | James L. McCarley, Jr.         | #2 Calle Nairn, Condo #1001, San Juan, PR 00907 |    |
|--|-----|--------------------------------|---|----|
|  |     | Name                           | Address   | -  |
|  | b)_ | Lynn H. McCarley               | #2 Calle Nairn, Condo #1001, San Juan, PR 00907 |    |
|  |     | Name                           | Address   | 7. |
|  | c)_ | N/A                            |   |    |
|  |     | Name                           | Address   | *  |
|  | d)_ | N/A                            |   |    |
|  | 10  | Name                           | Address   | -  |
|  | Pro | ovide the number of shares is  | sued by the corporation                         |    |
|  | Wł  | nat was the price paid per sha | re?\$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

<u>Certificate of Corporate Status</u> (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

2)

3)



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 Sates 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

7321 Cantrell Road • Little Rock, AR 72207 • Toll Free 877-666-5222 • www.cantrelldrug.com



GEORGIA DEPARTMENT OF COMMUNITY HEALTH

Frank Berry, Commissioner

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

September 26, 2017

Cantrell Drug Compañy 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 <u>bhowell@dch.ga.gov</u>.

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

Sincerely,

Georgia Board of Pharmacy

Equal Opportunity Employer

SUSAN ALVERSON R.Ph. Executive Secretary

Location: 111 Village Street Birmingham, AL 35242

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

## ALABAMA BOARD OF PHARMACY



#### MEMBERS 2017

BUDDY BUNCH, R.Ph. President

DAVID DARBY, R.Ph. Vice President

DONNA YEATMAN, R.Ph. Treasurer

RALPH SORRELL, R.Ph.

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 - <u>wpassmore@albop.com</u>

## IN THE MATTER OF:

## CANTRELL DRUG COMPANY

Manufacturer/Wholesaler/ Distributor Permit Number 194828

# BEFORE THE ALABAMA STATE BOARD OF PHARMACY

Case Number 16-0168

### FINAL ORDER

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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 <u>Code of Alabama</u> 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.

#### Page 1 of 3

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

Page 2 of 3

2. Upon submission by the Respondent of a letter to the Board describing the circumstances, reasons and factors by which the products listed on the "Tier One Product List" provided to the Board by the Respondent on April 18, 2017, are not commercially available, the Board shall not take the position that the products listed on the "Tier One Product are commercially available; and

3. Upon agreement by the Respondent and the Board, the Respondent shall notify the Board of any other products to be added to the above mentioned "Tier One Product List" and in the event the Respondent fails to so notify the Board of such products, the Board shall have the authority and jurisdiction to take disciplinary action it deems appropriate; and

4. Any future violations of this Order, the Alabama Pharmacy Practice Act, the laws that regulate the sale and or dispensing of prescription or legend drugs and or narcotics or any Rule of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state may, upon hearing and proof thereof, result in further disciplinary sanctions.

DONE and ORDERED, this 4th day of April 2017

Buddy Burch

Mr. Buddy Bunch, R. Ph., President Alabama State Board of Pharmacy

c: Mr. Michael W. Whisonant, Jr., Esq. Mr. H. Hube Dodd, Esq. Mr. James S. Ward, Esq. Dr. Susan Alverson, Executive Secretary Mr. Vance L. Alexander, Esq.

### SOUTH CAROLINA DEPARTMENT OF LABOR, LICENSING AND REGULATION BEFORE THE BEFORE THE STATE BOARD OF PHARMACY

#### IN THE MATTER OF:

#### CANTRELL DRUG COMPANY CANTRELL DRUG COMPANY INC 7321 Cantrell Rd. Little Rock, AR 72207 PY.10776 & PY.16647

#### FINAL ORDER (PUBLIC)

OIE # 2016-149

#### Respondent.

On March 15, 2017, the above licensing board ("Board"), with a quorum present, held a hearing on the Memorandum of Agreement and Stipulations ("MOA") in the above referenced matter entered into between the State and Respondent. The Board also heard Respondent's Petition to Resume Shipping Compounded Products. Patrick Hanks, Esquire, Chief Disciplinary Counsel, represented the State. Respondent was represented by Jon Wallace, Esquire. Dell McClary, CEO of Respondent; Dr. Eric Goode, Interim Chief of Compliance and Regulatory Affairs; and Ashley Wagener, Pharmacist in Charge, appeared on behalf of Respondent.

#### FINDINGS OF FACT

- 1. Respondent was properly served with a Notice of Hearing.
- 2. In the MOA, Respondent admitted to the following, which the Board adopts:
  - a. Respondent is an FDA Registered Outsourcing Facility under Section 503B of the Federal Food, Drug, and Cosmetic Act and is permitted in this state as a Nonresident Outsourcing facility, duly permitted by the State Board of Pharmacy (the "Board") in this State, and was so permitted at all times relevant to the matters asserted herein; thus, the Board has jurisdiction over this matter.
  - b. As a registered Outsourcing Facility under Section 503B of the Federal Food, Drug, and Cosmetic Act, Respondent must comply with cGMP requirements, be routinely inspected by FDA, and must meet certain other conditions, such as adverse event reporting, among other requirements.
  - c. FDA conducted an Outsourcing Facility Inspection of Respondent ending on October 14, 2016. As a result of the inspection, FDA issued Form 483 observations.
  - d. Respondent fully responded with a corrective action plan to the FDA Dallas District Office on November 4, 2016.

- e. In order to implement response items submitted to FDA, Respondent voluntarily ceased operations on November 2, 2016 and began to remediate issues raised by Form 483 observations. Respondent resumed operations on December 15, 2016, and currently, Respondent's facility is fully operational and is not restricted by the FDA.
- f. As an additional response to the Form 483 observations, on November 18, 2016, Respondent issued a voluntary recall of certain sterile drug products due to a potential lack of sterility assurance occurring over an isolated period of time. The recalled lots were only associated with any hood, gowning, or room out of specification. None of the recalled product revealed any contamination.
- g. Respondent entered into an engagement with ProPharma Group, which is a regulatory consulting company focused on cGMP compliance in the pharmaceutical industry.
- h. On November 22, 2016, the Board issued an Order restricting Respondent's distribution of sterile compounded products into South Carolina pending further order of the Board. Respondent hereby petitions the Board for relief from this Order.
- i. Prior to registering with FDA as an Outsourcing Facility, following an FDA inspection initiated on October 15, 2013, FDA issued a warning letter to Respondent.
- j. Arkansas Board of Pharmacy has taken no action in this matter, and Respondent's permit remains in good standing.

3. Since resuming operations in December of 2016, Respondent was inspected by a hospital collective and received a score of 97/100. The Board further finds that Respondent has implemented procedures to remedy the deficiencies noted by the FDA.

#### CONCLUSIONS OF LAW

- 1. Respondent was properly served with the Notice of Hearing.
- 2. The Board has jurisdiction in this matter.

3. Respondent acknowledged in the MOA that Respondent's conduct admitted in the MOA constitutes violations of S.C. Code Ann.  $\S$  40-43-86(DD)(5) and (EE), as well as 40-43-140(A)(1)(a). The Board adopts this conclusion.

4. Upon finding that a licensee's conduct is grounds for discipline under any of the provisions of S.C. Code Ann. §§ 40-1-110 or 40-43-10 *et seq.*, the Board has the authority to issue a public reprimand, impose a fine, place a licensee on probation or restrict the individual's license, suspend the license for a definite or indefinite time, prescribe conditions to be met during probation, restriction, or suspension including but not limited to completion of additional education, a supervisory period, continuing education programs, or permanently revoke the individual's license to practice pharmacy or registration as a pharmacy technician in this State. Additionally, S.C. Code Regs. 99-46

(2012, as amended) provides that upon determination by the Board that one or more grounds for disciplining a licensee or permittee exist, the Board may impose a fine of \$500 per violation, not to exceed a total of \$25,000 per action, plus the costs of the disciplinary action.

5. In this case, the Board concludes that Respondent may resume shipping compounded drugs into South Carolina subject to its compliance with certain conditions. First, Respondent's permit shall be placed on a probationary status for a minimum of two years. Prior to resuming shipping, Respondent must provide an inspection by the Arkansas Board of Pharmacy, which must be approved by the Board Administrator. Further, Respondent must provide an FDA End of Inspection ("EIR") Report indicating no further disciplinary action taken by the FDA. During Respondent's probationary period, Respondent must report any and all correspondence with the FDA to the Board Administrator. Respondent must reappear before the Board to have the probation lifted.

6. The sanctions and conditions imposed by this Order are within the scope of those permitted by S.C. Code Ann. §§ 40-1-120 and 40-43-150 (2011) and are designed not to punish the Respondent but to protect the life, health and welfare of the people at large.

#### **IT IS THEREFORE ORDERED:**

Act.

1. The Board accepts the MOA and finds that Respondent violated the Pharmacy Practice

2. The Petition to resume shipping compounded products is granted, subject to Respondent's submission to, and approval by, the Board Administrator of a new Arkansas inspection report. Upon receipt and approval of the same, the license shall be immediately placed on a probationary status for a period of two years, subject to the following conditions of probation: 1) Respondent must provide the Board with an FDA EIR Report indicating no further violations; 2) Respondent shall submit all correspondence, documentation, etc. received by the FDA to the Board; and 3) Respondent must reappear before the Board to have its permit removed from probationary status.

#### AND IT IS SO ORDERED.

#### STATE BOARD OF PHARMACY

revisell Morali

Carole Small Russell, R.Ph. Board Chair

September 19, 2017

# South Carolina Department of Labor, Licensing and Regulation

## STATE OF SOUTH CAROLINA

COUNTY OF LEXINGTON

In the Matter of:

CANTRELL DRUG COMPANY INC

PY . 10776

CERTIFICATE OF SERVICE BY MAIL

This is to certify that the undersigned has this date, September 19, 2017, served the Final Order in the above entitled action upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, or in the Interagency Mail Service addressed to the party(ies) or their attorney(s) to the following address:

CANTRELL DRUG COMPANY INC 7321 CANTRELL RD LITTLE ROCK AR 72207

JONATHAN A. WALLACE, ESQUIRE 715 KING STREET CHARLESTON, SC 29403

1 Rell

Karen Y. Newton Administrative Coordinator SC Department of Labor, Licensing and Regulation



## KENTUCKY BOARD OF PHARMACY

Matt Bevin Governor

> State Office Building Annex, Suite 300 125 Holmas Street Frankfort KY 40601 Phone (502) 584-7910 Fax (502) 696-3806 http://pharmacy.ky.goy

Board Members Deborah L. Brewer, R.Ph. Brlan C. DeWire, DC, Consumer Scott A. Greenwell, Pharm.D. Cathy Hanna, Pharm.D. Craig Martin, Pharm D. \* Ron Poole, R.Ph.

> Executive Director B. Steven Hart, R.Ph.

February 22, 2017

James McCarley Jr 7700 Northshore Place North Little Rock AR 72118

Re: Case No. 17-0202

Dear Pharmacist,

This letter follows a recent investigation by Board staff.

The purpose of this letter is to offer you an opportunity to informally resolve this matter through an Agreed Order prior to the filing of a formal Complaint. Find enclosed a proposed Agreed Order setting forth terms I believe the Board will accept.

Review the proposed Agreed Order carefully. Feel free to consult with legal counsel. If acceptable, sign and return the Agreed Order to the Board office by March 22, 2017. Upon receipt, the proposed Agreed Order will be signed by the Board President, and a copy will be sent to you.

If this proposed Agreed Order is unacceptable and you in good faith believe this matter can be resolved, please feel free to contact me during normal business hours.

Should you fail to respond by returning the proposed Agreed Order or contacting me by March 22, 2017, your case will be referred to the Office of the Attorney General to conduct an administrative hearing.

Sincere

Steve Hart, R.Ph. Executive Director

Enclosure



An Equal Opportunity Employer M/F/D

KentuckyUnbridledSpirit.com

## COMMONWEALTH OF KENTUCKY KENTUCKY BOARD OF PHARMACY Case No. 17-0202

## IN RE: PHARMACIST LICENSE NO. 013447 HELD BY James McCarley Jr

#### Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("Board") and James McCarley Jr ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is a pharmacist in the Commonwealth of Kentucky, having been assigned pharmacist license no. 013447.

(3)(a) Respondent self-reported completion of only 10 of 15 required hours of continuing education for the year 2016, in violation of 201 KAR 2:015, Section 5.

(b)

The above actions subject Respondent to discipline pursuant to KRS 315.121(1)(h).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined \$250.00, payable on or before March 22, 2017. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) On or before March 22, 2017, Respondent shall submit to the Board office proof of no less than ten (10) continuing education hours, which programs shall not be used in any way to satisfy Respondent's continuing education requirements for renewal.

(C) By entering into this Agreed Order, Respondent expressly acknowledges that the Respondent was fully and completely informed of Respondent's right to due process, that the Respondent fully understands those rights, and that the Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(D) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP") and is subject to disclosure under the Kentucky Open Records Act.

Scott Greenwell, President Kentucky Board of Pharmacy Date

2 Carlan P

James McCarley Jr, Respondent

Date

## U.S. Department of Justice



United States Attorney Eastern District of Arkansas

Post Office Box 1229 425 W. Capitol Avenue, Suite 500 Little Rock, Arkansas 72203 501-340-2600

FAX 501-340-2730

September 21, 2004

Mr. John Gilbert Hyman, Phelps & McNamara 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005-5929

RE: U.S. v. Cantrell Drive Store, Dell McCarley

Dear Mr. Gilbert:

Enclosed please find one executed copy of the Settlement Agreement. Thank you for your assistance in this matter.

Sincerely, H.E. (BUD) CUMMINS United States Attorney

By A. DOUG CHAVIS Assistant U.S. Attorney

ADC/kim

## UNITED STATES DISTRICT COURT EASTERN DISTRICT OF ARKANSAS WESTERN DIVISION

#### UNITED STATES OF AMERICA

V.

USAO: 2004V00173

CANTRELL DRUG STORE DELL MCCARLEY

#### SETTLEMENT AGREEMENT

This Settlement Agreement is made and entered into this 20 day of September, 2004, by and among the United States of America, acting through the United States Attorney for the Eastern District of Arkansas (hereinafter referred to as "USAO""), and Cantrell Drug Company.

#### PREAMBLE

WHEREAS, the United States contends that Cantrell Drug Company has violated 21

U.S.C. § 828(a), § 829(a) and § 842(a)(1), (a)(2) and (a)(5);

WHEREAS, the Cantrell Drug Company denies it has violated any provision of Title 21

U.S.C.

WHEREAS, the parties desire to reach an agreement that would settle, compromise and resolve the United States' claims under Title 21 U.S.C. in order to avoid the expense and uncertainty of litigation.

## **TERMS OF AGREEMENT**

NOW, THEREFORE, in reliance on the representations contained herein and in consideration of the mutual promises, covenants, and obligations in this Agreement, and for good and valuable consideration, receipt of which is hereby acknowledged, the parties agree as

1

follows:

1. Cantrell Drug Company agrees to pay \$30,000 (hereinafter the Settlement Amount), Said settlement amount shall be paid within 30 days of the date of this Agreement and paid as follows:

A \$10,000 check within 30 days of the date of the execution of this Settlement Agreement, a \$10,000 check within 120 days of the date of the execution of this Settlement Agreement and a \$10,000 check within 210 days of the date of the execution of this Settlement Agreement. Said checks shall be delivered to the office of the U.S. Attorney, Attn: Kim Squires, Legal Assistant, 425 W. Capitol, Suite 500, Little Rock, AR 72201.

Cantrell Drug Company also agrees to submit, within 30 days, an application with the U.S. Drug Enforcement Administration, for a manufacturer's registration.

2. In consideration of the agreements and payments set forth herein, the United States  $\cdot$  hereby releases and will be deemed to have released Cantrell Drug Company together with its owners, officers, employees, successors and assigns (hereinafter referred to as the "released persons and entities"), from any claims which the United States has or may have against the released persons arising from claims that may have occurred prior to and up to the date of this agreement under 21 U.S.C. § 828(a), § 829(a) and § 842(a)(1), (a)(2) and (a)(5).

3. The releases provided for in this Agreement shall not include releases from claims arising under Title 26 of the United States Code (Internal Revenue Code) and the regulations promulgated thereunder.

4. Each party to this Agreement shall bear its own costs.

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5. It is understood and agreed that this Settlement Agreement is in compromise of disputed claims and that it shall not be construed as an admission of or evidence of liability or wrongdoing on the part of any of the celeased chtitles.

6. This document contains the complete agreement between the parties with respect to the matters herein.

7. This Agreement may be executed in identical counterparts, each of which shall constitute an original and all of which shall constitute one and the same agreement.

8. This Agreement may be modified only by a written document signed by all of the parties. No waiver of this Agreement or of any of the promises, obligations, terms or conditions hereof shall be valid unless it is written and signed by the party against whom the waiver is to be enforced.

9. If any part or any provision of this Agreement shall be finally determined to be invalid or unenforceable under applicable law by a court of proper jurisdiction, that part shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining part of said provision or the remaining provision of this Agreement.

10. Each person who signs this Agreement in a representative capacity represents that he or she is duty authorized to do so.

11. This Agreement is effective upon the date of the signature of the last signatory.

IN WITNESS WHEREOF, we have hereunder set our hand as of the date first above written.

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On behalf of the United States of America, the Department of Justice, and acting through the United States Attorney for the Eastern District of Arkansas:

> H.E. (BUD) CUMMINS, United States Attorney

9-20-04 Date

By: ' A. Doug Chavis Assistant United States Attorney

On behalf of Cantrell Drug Company.

- 17 - 1º

Date

9/16/04

Date /

Dell McCarley, President Cantrell Drug Company

John Gilbert

Attorney for Cantrell Drug Company/ Hyman, Phelps & McNamara 700 Thirteenth Street, N.W., Suite 1200 Washington, D.C. 20005-5929