North Carolina Department of Agriculture and Consumer Services
Food & Drug Protection Division

Steve Troxler, Commissioner
Anita MacMullan, Director
Jeremy Evans, Drug Administrator

2024

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STATE USE ONLY

LICENSE NO.

RECEIVED:

Purpose of Application:

LICENSE TYPE / APPLICATION FEE:
(Choose selection with a '√')

- ☐ **Manufacturer - $1000**
- ☐ **Virtual Manufacturer - $1000**
- ☐ **Re-packager - $1000**
- ☐ **Outsourcing Facility (Sterile 503B) - $1000**
- ☐ **Distributor (in-state) - $ 700**
- ☐ **Wholesaler (out-of-state) - $ 700**
- ☐ **Reverse Distributor Only - $ 700**
- ☐ **Pseudoephedrine Only - $ 700**
- ☐ **Third Party Logistic Provider Only - $ 700**
- ☐ **Medical Gases Manufacturer - $1000**
- ☐ **Medical Gas Distributor (in-state) - $ 700**
- ☐ **Medical Gas Supplier (out-of-state) - $ 700**

APPLICATION TYPE
(Choose selection with a '√')

- ☐ **New Registration**
- ☐ **Renewal**
- ☐ **Change of Ownership**
- ☐ **Change In Location**

_____
CURRENT NC LICENSE/CERTIFICATE NO.
(Enter number from top right corner of NC license/registration)

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Location of Facility:
(Choose selection with a '√')

☐ **INSIDE NORTH CAROLINA**

Supplemental Documentation Required:
*Attach Printout of Current NC Business Registration
(Current NC Secretary of State Registration)

☐ **OUTSIDE NORTH CAROLINA**

Supplemental Documentation Required:
*Attach Printout of On-line Home State License Verification
*Attach Copy of Current Home State License

TYPE OF OWNERSHIP:
(Choose selection with a '√')

☐ **Individual** ☐ **Partnership** ☐ **LLC** ☐ **Corporation** _____
(Enter State of Inc.)

AFFILIATION:

Name or title under which business is conducted: _____
(Please list legal name and d.b.a. name if applicable)

Tax ID #: _____
(Federal Employer Identification Number – EIN)

Physical Address: _____
(P.O. Box not acceptable) Number and Street

_____ , _____ _____
City State Zip

Mailing Address: _____
(if different) Number and Street, City, State, Zip

Telephone Number: _____ **Fax Number:** _____

Email contact: _____
(Renewal notification in October based on e-mail address submitted on application; please notify us if this changes)

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Company Information:

NAMES OF OFFICERS/PARTNERS/MANAGERS:
(If more space is required, attach supplemental sheet(s) with identifying information.)

_____ _____
(President's Name) (Address)

_____ _____
(Vice President's Name) (Address)

_____ _____
(Secretary/Treasurer's Name) (Address)

FACILITY INFORMATION, IF APPLICABLE:
Please include name and address of all domestic and foreign facility affiliates, the name, phone number, and e-mail address for a responsible point of contact for each affiliate.
(If more space is required, attach supplemental sheet(s) with identifying information.)

Name: _____ Address: _____

Phone Number: _____ E-mail address: _____

EMPLOYEE TRAINING:
What education, training, experience, or combination of these are required of employees to assure assigned functions are performed in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law?
(If more space is required, attach supplemental sheet(s) with identifying information.)

_____

_____

LICENSURE / REGISTRATION QUESTIONS:
(Choose selection with a '√')

Has drug registration or license under any local, state, or federal law ever been suspended or revoked?
☐ **Yes** ☐ **No** (If yes, please attach an explanation and certified copies of all documents and records.)

Have you ever been denied issuance of, or pursuant to disciplinary proceedings, refused renewal of a license by any board or agency in North Carolina or any other state?
☐ **Yes** ☐ **No** (If yes, please attach an explanation and certified copies of all documents and records.)

Have any of the owners, partners of the firm, or officers of the corporation ever been convicted of any crime under the laws of the United States, North Carolina, or any other state pertaining to the manufacturing, distribution, sale or dispensing of drugs or narcotics?
☐ **Yes** ☐ **No** (If yes, please attach an explanation and certified copies of all documents and records.)

Do you compound and/or distribute Controlled Substances in North Carolina?
☐ **Yes** ☐ **No** (If yes, please list current DEA and NC-DHHS Registration Numbers)

DEA Registration Number: _____ **NC-DHHS Registration Number:** _____

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Applicant and On-Site Designated Representative:

I, the undersigned, do hereby certify that all the information contained in this application is complete, true, and correct. In addition, I agree that the business will be operated in compliance with all applicable Federal and State laws and regulations.

Date _____ Applicant Name_____
Owner, Partner, or Officer of Corporation

Title _____

Applicant Signature _____

Date _____ On-Site Designated Rep. Name: _____

Designated Rep. Signature _____

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Further Requirements Instructions:

Choose the form from the list below that corresponds to the 'License Type' you are applying for. **COMPLETE ONE FORM ONLY** per application and submit the completed form with pages 1-3 as indicated in the instructions. Type or print answers to all questions. Enter required information on all blanks and use 'Not Applicable' or 'N/A' where appropriate. Mark all areas with an '√' where indicated. If more space is required, attach supplemental sheet(s) identifying each item corresponding to the license application.
INCLUDE ALL REQUIRED SUPPLEMENTAL DOCUMENTATION AS INDICATED.

Choose only one form according to the list below that corresponds with the type of application you are applying for. EACH APPLICATION WILL SUBMIT ONLY ONE FORM PER APPLICATION.

FORM - LICENSE TYPE:

FORM A	**Manufacturer**
FORM B	**Virtual Manufacturer**
FORM C	**Re-packager**
FORM D	**Outsourcing Facility (Sterile 503B)**
FORM E	**Medical Gases Manufacturer**
FORM F	**Distributor (in-state);** **Wholesaler (out-of-state);** **Reverse Distributor Only;** **Pseudoephedrine Only;** **Third Party Logistic Provider Only;** **Medical Gas Distributor (in-state);** **Medical Gas Supplier (out-of-state)**

FORM A

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Manufacturer:

TYPE OF MANUFACTURER:
(Choose selection with a '√')

☐ **Title Holder – NDA(s) and/or ANDA(s) and/or BLA(s)**
☐ **Contract Manufacturer**
☐ **Other** _____
(Enter Description for 'Other')

FDA Registration:

Firm Name: _____

FDA Establishment Identifier (FEI#): _____

DUNS #: _____

Expiration Date: _____

NDC Labeler Code:

Firm Name: _____

Labeler Code: _____

National Drug Code listing:

NDA Number(s): _____

ANDA Number(s): _____

BLA Number(s): _____

Supplemental Documentation Required:

1. **Proof of Registration with the FDA**
   *Attach Printout of Current Registration from the 'Drug Establishments Current Registration Site' on FDA website (https://www.accessdata.fda.gov/scripts/cder/drls)

2. **Proof of listed NDA(s) and/or ANDA (s) and/or BLA (s)**
   *Attach Printout of Current Registration from the 'National Drug Code Directory' on FDA website of human prescription drug(s) listed under Firm Labeler Name and Code (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory)

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FORM B

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Virtual Manufacturer:

TYPE OF VIRTUAL MANUFACTURER:
(Choose selection with a '√')

☐ **Title Holder – NDA(s) and/or ANDA(s) and/or BLA(s)**

☐ **Other Agreement** _____
(Enter Description; *i.e. 'Co-licensing Agreement', etc)*

Home State License:

☐ **Yes** **License Type:** _____ **License Number:** _____

☐ **No** (Attach supporting documentation if Home State license not required)

NDC Labeler Code:

Firm Name: _____

Labeler Code: _____

National Drug Code listing:

NDA Number(s): _____

ANDA Number(s): _____

BLA Number (s): _____

Supplemental Documentation Required:

1. **Proof of listed NDA(s) and/or ANDA (s) and/or BLA (s)**
   *Attach Printout of Current Registration from the 'National Drug Code Directory' on FDA website of human prescription drug(s) listed under Firm Labeler Name and Code (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory)

2. **Proof of Other Agreement**
   (If Applicable)
   *Attach supporting documentation for type of Agreement Firm holds (as entered on 'Other Agreement' for *Type of Virtual Manufacturer* above), if Current Listing(s) from the 'National Drug Code Directory' on FDA website of human prescription drug(s) are listed under other Firm Name and Labeler Code in which Agreement is held.

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FORM C

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Re-Packager:

FDA Registration:

Firm Name: _____

FDA Establishment Identifier (FEI#): _____

DUNS #: _____

Expiration Date: _____

NDC Labeler Code:
(Enter if applicable)

Firm Name: _____

Labeler Code: _____

National Drug Code listing:
(Enter if applicable)

NDA Number(s): _____

ANDA Number(s): _____

BLA Number (s): _____

Supplemental Documentation Required:

1. **Proof of Registration with the FDA**
   *Attach Printout of Current Registration from the 'Drug Establishments Current Registration Site' on FDA website (https://www.accessdata.fda.gov/scripts/cder/drls)

2. **Proof of listed NDA(s) and/or ANDA (s) and/or BLA (s)**
   (If Applicable)
   *Attach Printout of Current Registration from the 'National Drug Code Directory' on FDA website of human prescription drug(s) listed under Firm Labeler Name and Code
   (https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory)

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FORM D

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Outsourcing Facility (Sterile 503B):

(Choose selection with a '√')

☐ **Yes** ☐ **No** **Indicate whether the facility intends to compound products on FDA's drug shortage**
For drugs compounded by registered outsourcing facilities that are on the FDA Shortage List, the drug must be compounded after the drug is placed on the drug shortage list and may not be dispensed or administered to a patient after it has been removed from the drug shortage list.

☐ **Yes** ☐ **No** **Indicate whether the facility compounds from bulk drug substances**
If any ingredients are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purposes of paragraph (3) of 353b, if any.

☐ **Yes** ☐ **No** **Licensed/registered in home state**

Home State License:

License Type: _____

License Number: _____

Pharmacist(s) in direct supervision of drug compounding operation:

Name (s): _____

License/Registration Number(s): _____

Supplemental Documentation Required:

1. **Proof of Registration with the FDA**
   *Attach Printout of Current Registration from the 'Registered Outsourcing Facilities Site' on FDA website (https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities)

2. **Most recent Inspection Report(s) and Observations**
   *Attach copy of most recent inspection report by appropriate regulatory agency (federal or state) including any findings, observations, and/or corrective actions.
   *Attach copies of Form FDA483 or warning letter issued relative to inspection, if applicable

3. **Response to Inspection Report(s)**
   *Attach copies of corrective actions provided in response to Form FDA 483, warning letter, or findings.

4. **Proof of valid license/registration to operate as a pharmacy**
   (If Applicable)

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FORM E

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Medical Gases Manufacturer:

FDA Registration:

Firm Name: _____

FDA Establishment Identifier (FEI#): _____

DUNS #: _____

Expiration Date: _____

Supplemental Documentation Required:

1. **Proof of Registration with the FDA**
   *Attach Printout of Current Registration from the 'Drug Establishments Current Registration Site' on FDA website (https://www.accessdata.fda.gov/scripts/cder/drls)

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FORM F

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Distributor (in-state) / Wholesaler (out-of-state) / Reverse Distributor Only/ Pseudoephedrine Only / Third Party Logistic Provider Only / Medical Gas Distributor (in-state) / Medical Gas Supplier (out-of-state):

Federal Background Check:

Federal Background Checks **Must Be Less Than Two Years Old.**

New Applications must submit a completed Federal Background Check for both the Applicant and On-Site Designated Representative from page 3 of the application (Instructions listed below).

Renewal Applications must submit a completed Federal Background Check for both the Applicant and On-Site Designated Representative from page 3 of the application **ONLY IF** the signatories are different personnel from the last application submitted or if the Designated Representatives are being updated (Instructions listed below). **The background check is not required if the signatories remain the same.**

Supplemental Documentation Required:

1. **Valid, Signed Driver License**
   *Attach a Copy of a valid, signed Driver License of the Applicant and On-Site Designated Representative from page 3 of the application.

2. **Completed Federal Background Check**
   *Attach Copy of each Federal Background Check received from the Applicant and On-Site Designated Representative from page 3 of the application after following the instructions below.

FEDERAL BACKGROUND CHECK INSTRUCTIONS:

Go to the www.fbi.gov/checks website, complete the Available Now: EDO process (the blue box) by first going to Option 1 HOW TO SUBMIT YOUR REQUEST ELECTRONICALLY – click on that link.

When you click on the link, a new page will open. When the page opens, it will say enter your email in the blue box. When you do that, we will send you an email with a PIN number on it – please write this down.

Then, you will click on the part that says "click here". This will take you to start the paperwork online – your registration. Fill out step by step. At the end, we will send you an email.

You will print the email and mail it to FBI CJIS Division – Summary Request, 1000 Custer Hollow Road, Clarksburg, WV 26306 unless otherwise noted **with your fingerprint card. I would pay the post office to put tracking on your envelope**. After we receive it, it will take approximately 7 business days to send it to you via email. If you would also like the hard copy response, please check the "preferences box" on the application to state that you would like the hard copy response in the mail/post.

- **Submit the report along with the completed license application to our department**
- **No license will be granted until all of this information is collected and reviewed.**

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Notice of Federal Background Check Required

The North Carolina Department of Agriculture and Consumer Services, Food and Drug Protection Division, requires applicants of Wholesale Prescription Drug Distributors to obtain and submit a federal background check report with the license application. The Food and Drug Protection Division will consider the following factors when reviewing any criminal convictions:

(1) The level and seriousness of the crime;
(2) The date of the crime;
(3) The age of the applicant at the time of the crime;
(4) The circumstances surrounding the commission of the crime, if known;
(5) The nexus between the criminal conduct and the prospective duties of the applicant as a licensee;
(6) The prison, jail, probation, parole, rehabilitation, and employment records of the applicant since the date the crime was committed;
(6a) The completion of, or active participation in, rehabilitative drug or alcohol treatment;
(6b) A Certificate of Relief granted pursuant to N.C. Gen. Stat. § 15A-173.2;
(7) The subsequent commission of a crime by the applicant; and
(8) Any affidavits or other written documents, including character references.

If the Food and Drug Protection Division denies a license application based on a criminal conviction, the applicant may appeal the denial in accordance with the North Carolina Administrative Procedures Act, N.C. Gen. Stat. § 150B-1 *et seq.* The applicant may commence the denial by filing a petition for a contested case hearing with the North Carolina Office of Administrative Hearings (OAH) within sixty (60) days at:

Office of Administrative Hearings
6714 Mail Service Center
Raleigh, NC 27699-6700

The petition must be in writing and in the form prescribed by N.C. Gen. Stat. § 150B-23 and accompanied by a filing fee established by OAH. The applicant must also serve a copy of the petition for a contested case hearing to:

Ms. Tina L. Hlabse
North Carolina Department of Agriculture and Consumer Services
Registered Agent and General Counsel
1001 Mail Service Center
Raleigh, NC 27699-1001

Any questions about filing a petition may be directed to the North Carolina Office of Administrative Hearings by telephone at (919) 431-3000. Information may also be obtained online at https://www.oah.nc.gov/hearings-division.