



**NORTH CAROLINA DEPARTMENT OF AGRICULTURE  
AND CONSUMER SERVICES  
FOOD AND DRUG PROTECTION DIVISION  
2018**

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

**STATE USE ONLY**

Check./M.O.# \_\_\_\_\_  
Received \_\_\_\_\_  
Amount \_\_\_\_\_  
License No. \_\_\_\_\_

**PURPOSE OF APPLICATION:  
LICENSE TYPE / APPLICATION FEE:**

- 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

**PURPOSE OF APPLICATION**

- New Registration
- Renewal
- Change of Ownership
- Change In Location
- Change In Facility Name

Previous Name: \_\_\_\_\_  
\_\_\_\_\_

**If you plan to compound and/or distribute Controlled Substances in North Carolina, this is another division and license. Please Contact [Cheanette.Hill@dhhs.nc.gov](mailto:Cheanette.Hill@dhhs.nc.gov) or 919-733-1765.**

Type or print answers to all questions. Use "Not Applicable" where appropriate. **If more space is required, attach supplemental sheets(s) identifying each item corresponding to the license application. Pay non-refundable fee by check or money order payable to "North Carolina Department of Agriculture & Consumer Services." DO NOT SEND CASH.**

**Location of Facility:**

IN NORTH CAROLINA  OUTSIDE NORTH CAROLINA **CURRENT NC LICENSE NUMBER** \_\_\_\_\_  
(Out-Of-State - Attach on-line verification)

Type of Ownership:  Individual  Partnership  Corporation  LLC State of Inc. \_\_\_\_\_

**Affiliation:**

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

Physical Address: \_\_\_\_\_  
(P.O. Box not acceptable) Number and Street City/State Zip

Mailing Address (if different): \_\_\_\_\_

Telephone Number \_\_\_\_\_ Fax Number: \_\_\_\_\_

E-Mail contact \_\_\_\_\_

**\*Renewal notification in October based on e-mail address submitted on application; please notify us if this changes**

**Names of officers/partners/managers:**

\_\_\_\_\_  
**(President's Name)**

\_\_\_\_\_  
**(Address)**

\_\_\_\_\_  
**(Vice President's Name)**

\_\_\_\_\_  
**(Address)**

\_\_\_\_\_  
**(Secretary/Treasurer's Name)**

\_\_\_\_\_  
**(Address)**

Type or print answers to all questions. Use "Not Applicable" where appropriate. **If more space is required, attach supplemental sheets(s) identifying each item corresponding to the license application.**

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

Name:

\_\_\_\_\_  
Address:

\_\_\_\_\_  
Phone number:

\_\_\_\_\_  
E-mail address:

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.)

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?

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Outsourcing Facility only (below)**

Each outsourcing facility at a separate geographic location or address must register separately.

Address	Telephone	Contact Person
_____	_____	_____
_____	_____	_____
_____	_____	_____

Indicate whether the facility intends to compound products on FDA’s drug shortage Yes \_\_\_ No \_\_\_  
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.

Indicate whether the facility compounds from bulk drug substances Yes \_\_\_ No \_\_\_  
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.

Licensed/registered in home state(attach copy of home state license & on-line verification or affidavit for out-of-state)Yes \_\_\_ No \_\_\_

Name and appropriate license/registration number of the pharmacist(s) in direct supervision of drug compounding operation. \_\_\_\_\_

Proof of valid license/registration to operate as a pharmacy, if applicable. \_\_\_\_\_

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; include corrective actions provided in response.

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**FURTHER REQUIREMENTS FOR THE FOLLOWING:**

1. **MANUFACTURER / VIRTUAL MANUFACTURER / REPACKAGER / OUTSOURCING FACILITY:**  
Must be registered with the FDA and / or have an approved labeler code(s) for the Product (s) with the FDA.

FEI # \_\_\_\_\_ DUNS # \_\_\_\_\_ UFI # \_\_\_\_\_  
NDC# \_\_\_\_\_ NDA# \_\_\_\_\_ ANDA# \_\_\_\_\_

2. **PROOF OF REGISTRATION WITH THE FDA (Attach a copy).**

3. **DISTRIBUTOR / REVERSE DISTRIBUTOR / WHOLESALER / THIRD PARTY LOGISTIC PROVIDER / PSEUDOEPHEDRINE ONLY:**

Complete below for **New** applications; Federal Background Checks **Must Be Less Than Two Years Old**

- A. Attach a **Copy Of A Valid, Signed Driver License Of The Applicant** To This Application.
- B. Submit a completed Federal Background Check (instructions listed below) for **each** facility manager and designated representative. No application will be accepted without these documents.

**FEDERAL BACKGROUND CHECK PROCEDURE**

- Go To Local Law Enforcement / Sheriff Office
- Request a Finger Print Card and Finger Printing (fee)
- Obtain A Money Order Written To: Treasurer Of The United States
- Submit: Finger Print Card
  - Money order (Call FBI 304-625-5590 for fee & FBI form OMB-1110-0052)
  - Cover letter / Full Name
  - Current Address
  - Phone Number
  - Reason for Request (licensing requirement)
- Place information in envelope and mail to the following address

FBI Record Request  
1000 Custer Hollow Road  
Clarksburg, West Virginia 26306

- In 10-12 weeks, you should have the report returned to you from the FBI
- 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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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 \_\_\_\_\_

**License expires December 31<sup>st</sup> of each year**  
**Changes in information supplied in this application must be submitted within 90 days.**

**Regular Mail:**

NCDA & CS  
Food & Drug Protection Division  
1070 Mail Service Center  
Raleigh, N.C. 27699-1070  
Telephone: 919-733-7366  
Fax: 919-733-6801  
Email: [Jeremy.Evans@ncagr.gov](mailto:Jeremy.Evans@ncagr.gov)  
[Shannon.Redd@ncagr.gov](mailto:Shannon.Redd@ncagr.gov)

**Overnight Mail (FedEx or UPS):**

NCDA & CS  
Food & Drug Protection Division  
4000 Reedy Creek Road  
Raleigh, N.C. 27607  
Attn: Shannon Redd

**Drug Laws & Regulations:**

[www.ncagr.gov](http://www.ncagr.gov)

STEVE TROXLER, COMMISSIONER  
FOOD AND DRUG PROTECTION DIVISION  
ANITA MACMULLAN, DIRECTOR  
1070 MAIL SERVICE CENTER, RALEIGH, NC 27699-1070  
TELEPHONE: (919) 733-7366 FAX: (919) 733-6801

**DRUG DISTRIBUTOR LICENSE VERIFICATION AFFIDAVIT**

**APPLICANT: COMPLETE ITEMS 1-7 ONLY, THEN FORWARD TO THE LICENSING AGENCY FOR THE STATE IN WHICH YOU ARE LOCATED. CHECK WITH THAT AGENCY FOR VERIFICATION OF FEE CHARGES. AFFIDAVIT IS TO BE FILLED OUT COMPLETELY WHEN RECEIVED IN THIS OFFICE.**

1. Name of Establishment to be Licensed \_\_\_\_\_

2. Address (Street, City, State, Zip Code) \_\_\_\_\_

3. Corporate Name \_\_\_\_\_

4. Type of Operation  Distributor/Wholesaler  Re-packager  Manufacturer  Re-labeler

5. Type of Drugs (Check all that apply)  Prescription  Controlled Substances

6. I HEREBY AUTHORIZE THE (your state licensing agency) \_\_\_\_\_ TO FURNISH TO THE N. C. DEPT. OF AGRICULTURE & CONSUMER SERVICES, FOOD AND DRUG PROTECTION DIVISION, THE INFORMATION REQUESTED BELOW.

7. Signature of Applicant (Corp., Partnership, Individual Owner) \_\_\_\_\_

**DO NOT WRITE BELOW THIS LINE – TO BE COMPLETED BY HOME STATE LICENSING AGENCY**

License Number \_\_\_\_\_ Date License Issued \_\_\_\_\_ Date License Expires \_\_\_\_\_

HAS THIS LICENSE BEEN ENCUMBERED IN ANY WAY? TYPE OF ENCUMBRANCE  
 YES  NO  REVOKED  SURRENDERED  LIMITED

8.  SUSPENDED  RESTRICTED  PROBATION  
PLEASE ATTACH CERTIFIED COPIES OF ALL PERTINENT LEGAL DOCUMENTS.

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS

Has the applicant been convicted under any federal, state or local laws relating to drug samples, wholesale  YES  NO or retail drug distribution, or distribution of controlled substances? (If yes, please explain.)

Has the applicant furnished any false or fraudulent material in any application made in connection with drug manufacturing or distribution? (If yes, please explain.)  YES  NO

Has any inspection of the applicant resulted in deficiency ratings? (If yes, please explain.)  YES  NO

Has the applicant met all licensing requirements of your state? (If not, please explain.)  YES  NO

BOARD SEAL AREA, AFFIX OFFICIAL STATE SEAL OF LICENSING AGENCY BELOW

NAME \_\_\_\_\_

9. STATE \_\_\_\_\_ TITLE \_\_\_\_\_

DATE \_\_\_\_\_ SIGNATURE \_\_\_\_\_