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 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 31st 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
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

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? ☐ YES ☐ NO

TYPE OF ENCUMBRANCE ☐ REVOKED ☐ SURRENDERED ☐ LIMITED ☐ SUSPENDED ☐ RESTRICTED ☐ PROBATION

8. 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 or retail drug distribution, or distribution of controlled substances? (If yes, please explain.) ☐ YES ☐ NO

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 _____