Manufacturer Application for Registration (Form DHHS 225-A)

NC Department of Health and Human Services

Division of Mental Health, Developmental Disabilities, and Substance Abuse Services – Drug Control Unit

3008 Mail Center Service Center

Raleigh, North Carolina 27699-3008

(919) 733-1765

Application Instructions – PLEASE READ THESE INSTRUCTIONS CAREFULLY

This application will be used by the North Carolina Department of Health and Human Services' Drug Control Unit to initiate a registration for the applicant under the North Carolina Controlled Substances Act of 1971 as well as assist in determining whether or not the applicant is in compliance with State and Federal laws pertaining to controlled substances. Therefore, please fill out this application in its entirety. Do not leave any fields blank, rather indicate that a field is not applicable by typing "N/A" in the space provided. Failure to complete the entire form will result in the application being returned to the applicant along with a request for additional information. To submit this Application for Registration, e-mail both the completed electronic PDF and a signed PDF copy to nccsareg@dhhs.nc.gov along with a signed PDF copy of an Applicant Disclosure of Loss, Diversion, or Destruction of Controlled Substances (Addendum to Forms DHHS 224 and 225). In accordance with 10A NCAC 26E.0104, the applicant must also submit a required, ***nonrefundable*** *application fee in the amount of $600.00.*

Attestation

By signing below, you attest that you are an administrator or an agent of the applicant who is authorized to answer the questions presented in this document. Furthermore, you attest that all of the information provided on this form is true, accurate, and complete to the best of your knowledge. All responses are subject to verification by the North Carolina Department of Health and Human Services' Drug Control Unit.

		Date	
Signature		**Phone Number**	
Name and Title		**E-Mail Address**	

Section A - Applicant Information

Facility Name			
Facility's Address		**Facility's County**	
Facility's State, City, Zip			
Mailing Address		**Facility's Phone Number**	
Mailing State, City, Zip			
Administrator	Name:	Title:	

Section B - Registration Classification

B1. Check all applicable drug schedules in which you are applying for:

- ☐ Schedule I
- ☐ Schedule II (Narcotic)
- ☐ Schedule IIN (Non-narcotic)
- ☐ Schedule III (Narcotic)
- ☐ Schedule IIIN (Non-narcotic)
- ☐ Schedule IV
- ☐ Schedule V
- ☐ Schedule VI (NC General Statutes §90-94)

B2. Are you currently authorized to manufacture, distribute, dispense, prescribe, conduct research, or otherwise handle controlled substances in the schedules for which you are applying under the laws of North Carolina or the Federal Government?	☐ Yes	☐ No
B3. Has the applicant been convicted of a felony under State or Federal law relating to the manufacture, possession, distribution, or dispensing of controlled substances?	☐ Yes	☐ No
B4. Has any previous registration held by the applicant, corporation, firm, partner, or officer of applicant under Federal CSA or NCCSA been surrendered, revoked, suspended, denied, or is it pending such action?	☐ Yes	☐ No

If you answered "Yes" to questions B3 and/or B4, please submit a letter along with this application setting forth the circumstances of such action.

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Section C - Manufacturing and Coincidental Activities

C1. List the DEA drug code numbers for all controlled substances in Schedule I, II, III, and IIIN that are manufactured at the applicant's facility. *Schedule VI refers to North Carolina's controlled substances schedule. If the applicant is not applying for Schedule I, Schedule II, and/or Schedule VI, please write/type "N/A" for this question.*

C2. Registration as a manufacturer permits inherent distribution privileges only to those substances that were manufactured by the applicant. Check schedules applicable to any category in the boxes below:

	Schedules					
Category	I	II	III	IV	V	VI
Bulk Manufacturer/Synthesizer-Extractor	☐	☐	☐	☐	☐	☐
Dosage Form Manufacturer	☐	☐	☐	☐	☐	☐
Repackager/Relabeler	☐	☐	☐	☐	☐	☐

Section D - Point of Contact

A Drug Control Inspector may conduct an unannounced inspection of the applicant's facility at some point during the registration period. Please provide a list of up to three individuals for whom the Inspector should ask for upon arrival at the facility. The names and titles provided should be listed in the desired order of contact and should include individuals who are knowledgeable of and possess some degree of responsibility for the disposition of controlled substances at the facility. Any phone numbers provided for points of contact in Section D should be a direct line in order to assist the Drug Control Unit with reaching the correct individual(s) if needed – the central phone number provided in Section A will serve as a backup. Please note that the Inspector may also interview other persons other than those listed below at his/her discretion.

Primary Contact	Name:	Title:
	E-mail:	Phone:
Secondary Contact	Name:	Title:
	E-mail:	Phone:
Tertiary Contact	Name:	Title:
	E-mail:	Phone:

Section E - State Registration History

E1. Please select the event below that best describes your reason for submitting an Application for Registration (Form DHHS 225) and provide an answer to each supporting question for that event *(choose only one answer from below)*

☐ The application is for a new manufacturer / first time registrant

Anticipated Opening Date:

☐ The application reflects a name change for a registrant

Name on Previous Registration:

Previous DHHS Registration No:

☐ The application reflects a change of location/address for a registrant

Name on Previous Registration:

Previous Address (Line 1):

☐ The application reflects a change in ownership

Name on Previous Registration:

Previous DHHS Registration No:

Previous Address (Line 2):		Was Business Sold or Merged:	
Previous City:		Percentage of Ownership Sold:	
Previous DHHS Registration No:		Corporate or Branch Level Sold:	

Section F - Drug Enforcement Administration (DEA) Registration

F1. Does the applicant currently possess any controlled substances? ☐ Yes ☐ No

F2. What is the current status of the applicant's DEA Registration? *(choose only one answer from below and provide the requested information)*

☐ Valid Registration in possession	Name on Registration:	DEA Number:
☐ Applied for Registration	Applicant's Name:	Date Applied:
☐ DEA Registration will be applied for pending approval of NC DHHS Registration		
☐ Other *(explain)*:		

F3. Who is responsible for controlled substances? *(this is the individual who signed DEA Form 224):*

F4. Has the applicant granted Power of Attorney to any individuals for ordering controlled substances? ☐ Yes ☐ No

If yes, please provide the name(s) of the individual(s):

Section G - Storage and Security

G1. Describe the storage and security of the facility's controlled substances inventory. Include a detailed description of the facility's alarm system, entry points, location of controlled substance storage area, and backup security system in the event of a power loss.

G2. List all employees responsible for handling controlled substances at the facility. Are there any employees with a controlled substance related felony charge?

Section H - Records

H1. Biennial Inventory Date

H2. Describe the procedure for purchasing and receiving Schedule I, Schedule II, and Schedule VI controlled substances. How are DEA Form-222s, invoices, and any other documents acknowledging the purchase and receipt of Schedule I and Schedule II controlled substances recorded and maintained? *Schedule VI refers to North Carolina's controlled substances schedule. If the applicant is not applying for Schedule I, Schedule II, and/or Schedule VI, please write/type "N/A" for this question.*

H3. Describe the procedure for purchasing and receiving Schedule III, IV, and V controlled substances. How are pharmacy provider requisition forms, invoices, and any other documents acknowledging the purchase and receipt of Schedule III, IV, and V controlled substances recorded and maintained? *If the applicant is not applying for Schedule III, IV, and/or V, please write/type "N/A" for this question.*

H4. Describe the procedure for distributing controlled substances. What type of records are maintained to document the distribution (i.e. manifests, customer orders, etc.)?

Section I - Effective Controls for the Prevention of Diversion

I1. Other than physical security measures that have already been discussed in previous sections of this document, what steps is the applicant taking to maintain effective controls for the prevention of diversion of controlled substances? Answers should include, but are not limited to, software reporting systems being utilized to monitor user and drug activity as well as the frequency and individuals involved in the review of such material.

Section J - Supplemental Materials

The following documents are required as part of your Application for Registration:

1. *Copy of the applicant's current DEA Registration*
2. *A schematic or illustration that details the facility's security measures, entry points, and location of controlled substance storage area.*