



# Analytical Laboratory Application for Registration (Form DHHS 225-D)

## 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](mailto: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 \$100.00.

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

<b>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?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>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?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
<b>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?</b>	<input type="checkbox"/> Yes	<input type="checkbox"/> 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.

**Section C - Point of Contact**

A Drug Control Inspector will 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 C 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.

<b>Primary Contact</b>	Name:	Title:
	E-mail:	Phone:
<b>Secondary Contact</b>	Name:	Title:
	E-mail:	Phone:
<b>Tertiary Contact</b>	Name:	Title:
	E-mail:	Phone:

**Section D - State Registration History**

**D1. 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)**

<input type="checkbox"/> The application is for a new laboratory / first time registrant Anticipated Opening Date: _____	<input type="checkbox"/> The application reflects a name change for a registrant Name on Previous Registration: _____ Previous DHHS Registration No: _____
<input type="checkbox"/> The application reflects a change of location/address for a registrant Name on Previous Registration: _____ Previous Address (Line 1): _____ Previous Address (Line 2): _____ Previous City: _____ Previous DHHS Registration No: _____	<input type="checkbox"/> The application reflects a change in ownership Name on Previous Registration: _____ Previous DHHS Registration No: _____ Was Business Sold or Merged: _____ Percentage of Ownership Sold: _____ Corporate or Branch Level Sold: _____

**Section E - Drug Enforcement Administration (DEA) Registration**

**E1. Does the applicant currently possess any controlled substances?**  Yes  No

**E2. What is the current status of the applicant's DEA Registration? (choose only one answer from below and provide the requested information)**

<input type="checkbox"/> Valid Registration in possession	Name on Registration: _____	DEA Number: _____
<input type="checkbox"/> Applied for Registration	Applicant's Name: _____	Date Applied: _____
<input type="checkbox"/> DEA Registration will be applied for pending approval of NC DHHS Registration		
<input type="checkbox"/> Other (explain): _____		

**E3. Who is responsible for controlled substances? (this is the individual who signed DEA Form 224):**

**E4. 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 F - Storage and Security

**F1. How many total storage locations are utilized for the storage of controlled substances at the facility? Describe the type of storage equipment for each location (i.e. wall cabinet, combination safe, keyed safe, etc.).**

**F2. How is access to the controlled substance inventory location(s) controlled? List the persons and/or titles and number of individuals with access, describe how key control is practiced, and provide any other information deemed pertinent to assuring the security of controlled substances at the facility.**

## Section G - Records

**G1. Biennial Inventory Date**

**G2. Describe the procedure for obtaining controlled substances. What records are maintained to document the receipt and utilization of controlled substances?**

## Section H - Effective Controls for the Prevention of Diversion

**H1. 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.**