

## SUBCHAPTER 26F – CONTROLLED SUBSTANCES

### SECTION .0100 - SCHEDULES OF CONTROLLED SUBSTANCES

#### 10A NCAC 26F .0101 DEFINITIONS

As used in this Section, the following terms shall have the meanings specified:

- (1) The term "act" means the North Carolina Controlled Substances Act (G.S. Chapter 90, Article 5).
- (2) The term "basic class" means, as to controlled substances listed in Schedules I, II and VI:
  - (a) Each of the opiates, including its isomers, esters, ethers, salts and salts of isomers, esters, ethers and salts is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;
  - (b) Each of the opium derivatives, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;
  - (c) Each of the hallucinogenic substances, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Schedule I of the North Carolina Controlled Substances Act;
  - (d) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis:
    - (i) opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
    - (ii) apomorphine;
    - (iii) codeine;
    - (iv) etorphine hydrochloride;
    - (v) ethylmorphine;
    - (vi) hydrocodone;
    - (vii) hydromorphone;
    - (viii) metopon;
    - (ix) morphine;
    - (x) oxycodone;
    - (xi) oxymorphone;
    - (xii) thebaine;
    - (xiii) mixed alkaloids of opium listed in Schedule I of the North Carolina Controlled Substances Act;
    - (xiv) cocaine; and
    - (xv) ecgonine;
  - (e) Each of the opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters and ethers, and salts is possible within the specific chemical designation, listed in Schedule II of the North Carolina Controlled Substances Act;
  - (f) Methamphetamine, its salts, isomers and salts of its isomers;
  - (g) Amphetamine, its salts, optical isomers and salts of its optical isomers;
  - (h) Phenmetrazine and its salts;
  - (i) Methylphenidate;
  - (j) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers and salts of isomers whenever the existence of such salts, isomers and salts of isomers is possible within the specific chemical designation listed in Rule .0205 of this Section.
- (3) The term "hearing" means any hearing held pursuant to this part for the addition, deletion or rescheduling of any substances within Schedules I through VI of the North Carolina Controlled Substances Act.

- (4) The term "isomer" means, except as used in Paragraph .0202(d) of this Section, the optical isomer. As used in Paragraph .0202(d) of this Section, the term "isomer" means the optical, position or geometric isomer.
- (5) The term "interested person" means any person affected by any decision issuable pursuant to General Statute 90-88.
- (6) The term "proceeding" means all actions taken for the addition, deletion, or rescheduling of any substance within Schedules I through VI of the North Carolina Controlled Substances Act, issued pursuant to General Statute 90-88, commencing with the publication by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services of the proposed addition, deletion or rescheduling.
- (7) The term anabolic steroid means any drug or hormonal substance, chemically and pharmacologically related to testosterone (other than estrogens, progestins, and corticosteroids) that promotes muscle growth, and includes:
- (a) Boldenone;
  - (b) Chlorotestosterone (4-chlortestosterone);
  - (c) Clostebol;
  - (d) Dehydrochlormethyltestosterone;
  - (e) Dihydrotestosterone (4-dihydrotestosterone);
  - (f) Drostanolone;
  - (g) Ethylestrenol;
  - (h) Fluoxymesterone;
  - (i) Formebolone (formebolone);
  - (j) Mesterolone;
  - (k) Methandienone;
  - (l) Methandranone;
  - (m) Methandriol;
  - (n) Methandrostenolone;
  - (o) Methenolone;
  - (p) Methyltestosterone;
  - (q) Mibolerone;
  - (r) Nandrolone;
  - (s) Norethandrolone;
  - (t) Oxandrolone;
  - (u) Oxymesterone;
  - (v) Oxymetnolone;
  - (w) Stanolone;
  - (x) Stanozolol;
  - (y) Testolactone;
  - (z) Testosterone;
  - (aa) Trenbolone; and
  - (bb) Any salt, ester, or isomer of a drug or substance described or listed in this Paragraph, if that salt, ester, or isomer promotes muscle growth. Except such term does not include an anabolic steroid which is expressly intended for administration through implants to cattle or other nonhuman species and which has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this Paragraph.
- (8) Any term not defined in this Rule shall have the definition set forth in General Statute 90-87.

*History Note: Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. September 1, 1998; August 1, 1991; May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

## 10A NCAC 26F .0102 SCHEDULE I

(a) Schedule I shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-89. Each drug or substance has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.11.

(b) The Commission for MH/DD/SAS may add, delete, or reschedule substances within Schedules I-VI as specified in G.S. 90-88.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Stimulants:

- (1) 2, 5 - Dimethoxy-4-(n)- propylthiophenethylamine; and
- (2) N-Benzylpiperazine.

(d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Hallucinogenic substances:

- (1) Alpha-Methyltryptamine;
- (2) 5-Methoxy-N, N-diisopropyltryptamine;
- (3) methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3-methylbutanoate, (FUB-AMB, MMB-FUBINACA, AMB-FUBINACA) DEA controlled substances code number 7021;
- (4) methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3-methylbutanoate (Other names: MMB-CHMICA; AMB-CHMICA) DEA controlled substances code number 7044;
- (5) N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (Other name: 5F-AB-PINACA) DEA controlled substances code number 7025;
- (6) Naphthalen-1-yl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (Other names: NM2201; CBL2201) DEA controlled substances code number 7221;
- (7) 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-pyrrolo[2,3-b]pyridine-3-carboxamide (Other name: 5F-CUMYL-P7AICA) DEA controlled substances code number 7085;
- (8) 1-(4-cyanobutyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (Other names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78) DEA controlled substances code number 7089;
- (9) N-ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) DEA controlled substances code number 7543; and
- (10) 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-methoxymethamphetamine, PMMA) DEA controlled substances code number 1245.

(e) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substance within Schedule I for Opiates:

- (1) para-Methoxybutyryl fentanyl (N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)butyramide) DEA controlled substances code number 9837;
- (2) Cyclopentyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopentanecarboxamide) DEA controlled substances code number 9847;
- (3) Isobutyryl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylisobutyramide) DEA controlled substances code number 9827;
- (4) para-Chloroisobutyryl fentanyl (N-(4-chlorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) DEA controlled substances code number 9826;
- (5) Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide) DEA controlled substances code number 9844;
- (6) Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide; also known as benzoyl fentanyl) DEA controlled substances code number 9841;
- (7) para-Methylfentanyl (N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) DEA controlled substances code number 9817;
- (8) ortho-Methyl methoxyacetyl fentanyl (2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) DEA controlled substances code number 9820;
- (9) ortho-Methyl acetylfentanyl (N-(2-methylphenyl)-N-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) DEA controlled substances code number 9848;
- (10) Thiofuranyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl) DEA controlled substances code number 9839;

- (11) beta-Methyl fentanyl (N-phenyl-N-(1-(2-phenylpropyl)piperidin-4-yl)propionamide; also known as  $\beta$ -methyl fentanyl) DEA controlled substances code number 9856;
- (12) beta-Phenyl fentanyl (N-(1-phenethylpiperidin-4-yl)-N,3-diphenylpropanamide; also known as  $\beta'$ -phenyl fentanyl; 3-phenylpropanoyl fentanyl) DEA controlled substances code number 9842;
- (13) 2'-Fluoro ortho-fluorofentanyl (N-(1-(2-fluorophenethyl)piperidin-4-yl)-N-(2-fluorophenyl)propionamide; also known as 2'-fluoro 2-fluorofentanyl) DEA controlled substances code number 9855;
- (14) 4'-Methyl acetyl fentanyl (N-(1-(4-methylphenethyl)piperidin-4-yl)-N-phenylacetamide) DEA controlled substances code number 9819;
- (15) ortho-Fluorobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) DEA controlled substances code number 9846;
- (16) Fentanyl carbamate (ethyl (1-phenethylpiperidin-4-yl)(phenyl)carbamate) DEA controlled substances code number 9851;
- (17) ortho-Fluoroacryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)acrylamide) DEA controlled substances code number 9852;
- (18) para-Fluoro furanyl fentanyl (N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) DEA controlled substances code number 9854; and
- (19) ortho-Fluoroisobutyryl fentanyl (N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide) DEA controlled substances code number 9853.

*History Note:* Authority G.S. 90-88; 90-89; 143B-147;  
 Eff. June 30, 1978;  
 Amended Eff. November 1, 2005; July 1, 1995; November 1, 1994; April 1, 1994; January 1, 1994;  
 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;  
 Amended Eff. December 1, 2021.

#### **10A NCAC 26F .0103 SCHEDULE II**

- (a) Schedule II shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-90. Each drug or substance has been assigned the Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.12.
- (b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Lisdexamfetamine, its salts, isomers, and salts of its isomers to Schedule II for Stimulants.
- (c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Tapentadol, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers to Schedule II for Opiates.
- (d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds fentanyl immediate precursor chemical, N-phenyl-N-(piperidin-4-yl) propionamide (norfentanyl), DEA controlled substances code number 8366, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers, to Schedule II for Opiates.
- (e) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Oliceridine (N-[(3-methoxythiophen-2-yl)methyl]({2-[(9R)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine), DEA controlled substances code number 9245, its esters, ethers, salts, isomers and salts of its isomers, esters and ethers, to Schedule II for Opiates.

*History Note:* Authority G.S. 90-88; 90-90; 143B-147;  
 Eff. June 30, 1978;  
 Amended Eff. January 1, 1994; April 1, 1993; August 1, 1991; August 1, 1989;  
 Temporary Amendment Eff. May 13, 1997;  
 Amended Eff. February 1, 2010; June 1, 2009; August 1, 2002; July 1, 1998;  
 Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;  
 Amended Eff. December 1, 2021.

#### **10A NCAC 26F .0104 SCHEDULE III**

- (a) Schedule III shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated and as specified in G.S. 90-91. Each drug or substitute has been assigned the

Drug Enforcement Administration controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.13.

(b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Embutramide to Schedule III for Depressants.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds Buprenorphine to Schedule III for Narcotic Drugs.

(d) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds for anabolic steroids, including their salts, esters and ethers:

- (1) Boldione (androsta-1,4-diene-3,17-dione);
- (2) Desoxymethyltestosterone (17[alpha]-methyl-5[alpha]-androst- 2-en-17[beta]-ol) (a.k.a., madol); and
- (3) 19-nor-4,9(10)- androstadienedione (estra-4,9(10)-diene- 3,17-dione).

*History Note: Authority G.S. 90-88; 90-91; 143B-147;  
Eff. June 30, 1978;  
Amended Eff. July 1, 2011; June 1, 2009; August 1, 2002; August 1, 1991; December 1, 1987; August 1, 1987; July 1, 1982;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0105 SCHEDULE IV**

(a) Schedule IV shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and listed in either G.S. 90-92 or this Rule. Each drug or substance has been assigned the Drug Enforcement Administration (DEA) controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.14.

(b) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substances within Schedule IV for Depressants:

- (1) Dichloralphenazone - DEA controlled substances code number 2467;
- (2) Zopiclone - DEA controlled substances code number 2784;
- (3) Fospropol - DEA controlled substances code number 2138;
- (4) Carisoprodol - DEA controlled substances code number 8192;
- (5) Lemborexant - DEA controlled substances code number 2245; and
- (6) Remimazolam - DEA controlled substances code number 2846.

(c) As specified in G.S. 90-88, the Commission for MH/DD/SAS adds the following substances within Schedule IV for Stimulants: Serdexmethylphenidate – DEA controlled substances code number 1729.

*History Note: Authority G.S. 90-88; 90-92; 143B-147;  
Eff. June 30, 1978;  
Amended Eff. July 1, 1993; January 1, 1989; December 1, 1987; August 1, 1987;  
Temporary Amendment Eff. May 28, 1998;  
Temporary Amendment Expired March 12, 1999;  
Amended Eff. August 1, 2000;  
Temporary Amendment Eff. January 1, 2002; February 15, 2001;  
Amended Eff. July 1, 2012; July 1, 2011; November 1, 2005; April 1, 2003; August 1, 2002;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;  
Amended Eff. December 1, 2021.*

#### **10A NCAC 26F .0106 SCHEDULE V**

(a) Schedule V shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name, or brand name designated and listed in either G.S. 90-93 or this Rule. Each drug or substance is set forth in this Rule with its corresponding Drug Enforcement Administration (DEA) controlled substances code number set forth in the Code of Federal Regulations, Title 21, Section 1308.15.

(b) Narcotic drugs containing non-narcotic active medicinal ingredients. Any compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth in this Paragraph, which shall include one or more non-narcotic active medicinal ingredients in

sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

- (1) not more than 200 milligrams of codeine per 100 milliliters or per 100 grams,
- (2) not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams,
- (3) not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams,
- (4) not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit,
- (5) not more than 100 milligrams of opium per 100 milliliters or per 100 grams,
- (6) not more than 0.5 milligrams of difenoxin and not less than 25 micrograms atropine sulfate per dosage unit.

(c) Stimulants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers: Pyrovalerone - DEA controlled substances code number 1485.

(d) Depressants. Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

- (1) Lacosamide – DEA controlled substances code number 2746;
- (2) Ezogabine – DEA controlled substances number 2779;
- (3) Cenobamate – DEA controlled substances number 2720; and
- (4) Lasmiditan – DEA controlled substances number 2790.

*History Note:* Authority G.S. 90-88; 90-93; 143B-147;  
Eff. June 30, 1978;  
Amended Eff. July 1, 2012; February 1, 2010; April 1, 1992; August 1, 1988; December 1, 1987;  
April 1, 1983;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016;  
Amended Eff. December 1, 2021; March 1, 2021; January 1, 2019.

#### **10A NCAC 26F .0107 SCHEDULE VI**

(a) Schedule VI shall consist of the drugs and other substances by whatever official name, common or usual name, chemical name or brand name designated listed in this Rule. Each drug or substance has been assigned the Drug Enforcement Administration code number set forth opposite it:

Tetrahydrocannabinols	7370
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(b) Synthetic equivalents of the substances contained in the plant or in the resinous extractives of cannabis, and/or synthetic substances, derivatives and their isomers with similar chemical structure and pharmacological activity such as the following:

- 1 cis or trans tetrahydrocannabinol and their optical isomers.
- 6 cis or trans tetrahydrocannabinol and their optical isomers.
- 3, 4 cis or trans tetrahydrocannabinol and its optical isomers.

(Since nomenclature of these substances is not internationally standardized, compounds of these structures, regardless of numerical designation, designations of atomic position are covered.)

Marijuana	7360
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*History Note:* Authority G.S. 90-88(a);  
Eff. June 30, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0108 APPLICATION FOR EXCLUSION OF NONNARCOTIC SUBSTANCE**

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug and Cosmetic Act (21 USC 301), as amended, be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to General Statute Chapter 90-88(e) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exclusion under this Section shall contain the following information:

- (1) the name and address of the applicant,
- (2) the name and the substance for which exclusion is sought, and
- (3) the complete quantitative composition of the substance.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may reject an application for filing, giving the reason therefor, if any of the requirements prescribed in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraph (b) of this Rule. If accepted for filing, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall publish general notice in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure that it will make a determination on the application at its next regularly scheduled meeting. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall permit any interested person to file written comments or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(d) After consideration of the application and any comments on or objections to its proposed decision at its next regularly scheduled meeting, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall issue and publish in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure its final order on the application. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

(e) In the event a nonnarcotic substance no longer meets the criteria in G.S. 90-88(e), the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke any exclusion granted pursuant to G.S. 90-88(e) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exclusion which has been accepted for filing.

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0109 EXCLUDED SUBSTANCES**

Those drugs which were excluded by the Drug Enforcement Administration on April 1, 1973, under Section 201(g)(1) of Federal Controlled Substances Act [21 USC 811(g)(1)], as amended, have been excluded by the Drug Commission from all schedules pursuant to General Statute Chapter 90-88(e).

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. September 30, 1978;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0110 APPLICATION FOR EXEMPT CHEMICAL PREPARATIONS**

(a) Any person seeking to have any preparation or mixture containing controlled substances and one or more noncontrolled substances exempted from the application of all or any part of the act pursuant to General Statute Chapter 90-88(g) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exemption under this Rule shall contain the following information:

- (1) the name, address and registration number, if any, of the applicant;
- (2) the name, address and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;
- (3) the exact trade name or other designation of the preparation or mixture;
- (4) the complete quantitative composition of all the preparation or mixture (including all active ingredients and noncontrolled substances);

- (5) the form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);
- (6) the dimensions or capacity of the immediate container of the preparation or mixture;
- (7) the label and labeling, as defined in Rule .0201 of Subchapter 26E of this Chapter and of G.S. 90-106, the North Carolina Controlled Substances Act, as amended, of the immediate container and the commercial containers, if any, of the preparation or mixture;
- (8) a brief statement of the facts which the applicant believes justify the granting of an exemption under this Paragraph including information on the use to which the preparation or mixture will be put;
- (9) the date of application; and
- (10) which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under any law restricting public disclosure of information.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may require the applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted.

(d) Within a reasonable period of time after the receipt of an application for an exemption under this Rule, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall notify the applicant of its acceptance or nonacceptance of his application and, if not accepted, the reason therefor. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services need not accept an application for filing if any of the requirements prescribed in Paragraph (b) of this Rule or requested pursuant to Paragraph (c) of this Rule is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraphs (b) and (c) of this Rule. If the application is accepted, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall issue and publish in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure its final order on the application. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

(e) In the event a preparation or mixture containing controlled substance no longer meets the criteria in G.S. 90-88(e) for being excluded, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke or modify any exemption granted pursuant to this Section by following the procedure set forth in Paragraph (d) of this Rule for handling an application for exemption.

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0111 EXEMPT CHEMICAL PREPARATIONS**

Those drugs which were exempted by the Drug Enforcement Administration on April 1, 1973, under Sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003, 1004 of the Federal Controlled Substances Act (21 USC 822-3, 825-9, 952-4) as amended, have been exempted by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services to the same extent described in 21 CFR 308.24(b) through (h) pursuant to G.S. 90-88(g).

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0112 APPLICATION FOR EXCEPTION OF A STIMULANT OR DEPRESSANT**



(a) Any person seeking to have any compound, mixture or preparation containing any depressant or stimulant substance listed in Paragraph .0204(b) or (c) or in Rule .0205 or in .0206 of this Section excepted from the application of all or any part of the act, pursuant to G.S. 90-91(i) and 90-92(b), may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exception under this Rule shall contain the following information:

- (1) the complete quantitative composition of the dosage form,
- (2) description of the unit dosage form together with complete labeling,
- (3) a summary of the pharmacology of the product including animal investigations and clinical evaluations and studies with emphasis on the psychic or physiological dependence liability, (This must be done for each of the active ingredients separately and for the combination product.)
- (4) details of dynergisms and antagonisms among ingredients,
- (5) deterrent effects of the noncontrolled ingredients,
- (6) complete copies of all literature in support of claims,
- (7) reported instances of abuse,
- (8) reported and anticipated adverse effects,
- (9) number of dosage units produced for the past two years.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may reject an application for filing, giving the reason therefor, if any of the requirements prescribed in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraph (b) of this Rule. If accepted for filing, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall publish general notice in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure that it will make a determination on the application at its next regularly scheduled meeting. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(d) After consideration of the application and any comments on or objections to its proposed decision at its next regularly scheduled meeting, the Director shall issue and publish its final order on the application in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Director finds that conditions of public health or safety necessitate an earlier effective date in which event the Director shall specify in the order its findings as to such conditions.

(e) The Director may at any time revoke any exception granted pursuant to G.S. 90-91 or G.S. 90-92(b) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exception which has been accepted for filing.

*History Note: Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990; May 15, 1979;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0113 EXCEPTED COMPOUNDS**

Those drugs which were excepted by the Drug Enforcement Administration April 1, 1973, under Section 202(d) of the Federal Controlled Substances Act [21 USC 812(d)] as amended have been excepted by the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services from application of G.S. 90-104, 90-105 and 90-106. Any deviation from the quantitative composition of any of the listed drugs shall require a petition for exception in order for that drug to be excepted.

*History Note: Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0114 HEARINGS GENERALLY**

In any case where the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall hold a hearing on the addition, deletion or rescheduling of substances within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to G.S. 90-88, the procedures for such hearings and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in G.S. 150B and specifically by G.S. 90-88 and by these rules and regulations, Departmental rules.

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0115 PURPOSE OF HEARING**

The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall hold a hearing for the purpose of receiving factual evidence regarding the issues involved in the addition, deletion or rescheduling with Schedules I through VI of the North Carolina Controlled Substances Act.

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0116 WAIVER OR MODIFICATION OF RULES**

The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may modify or waive any rule in this part by notice in advance of the hearing with the consent of the parties to the hearing if it determines that no party in the hearing will be unduly prejudiced and the ends of justice will thereby be served. Such notice of modification or waiver shall be made a part of the record of the hearing.

*History Note:* Authority G.S. 90-88; 150B-25;  
Eff. June 30, 1978;  
Amended Eff. May 1, 1990;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0117 ADDITION: DELETION OR RESCHEDULING OF A SUBSTANCE**

(a) Any interested person may submit a petition to initiate proceedings for the addition, deletion or rescheduling of any substances within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to the provisions of G.S. 90-88.

(b) Petitions shall be submitted in quintuplicate to the Commission for Mental Health, Mental Retardation and Substance Abuse Services in the following form:

\_\_\_\_\_  
Date

(The Commission Address)

Dear Sir: The undersigned \_\_\_\_\_ hereby petitions the commission to initiate proceedings for the addition (deletion or rescheduling) of a substance within Schedules I through VI of the North Carolina Controlled Substances Act pursuant to G.S. 90-88.

Attached hereto and constituting a part of this petition are the following:

- (1) the proposed substance in the form proposed by the petitioner; (If the petitioner seeks the deletion or rescheduling of an existing controlled substance, the existing controlled substance together with a reference to this Section in the latest commission publication of Schedules I through VI where it appears should be included.)

- (2) a statement of the grounds which the petitioner relies upon for the addition (deletion or rescheduling) of the substance. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City and State

Respectfully yours,

\_\_\_\_\_  
Signature of Petitioner

(c) The commission may reject a petition for filing if any of the requirements in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If petitioner desires, he may amend the petition to meet the requirements of Paragraph (b) of this Rule.

(d) When the commission holds a hearing pursuant to G.S. 90-88(a), it shall publish in newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure general notice of any proposed addition, deletion or rescheduling of a substance pursuant to G.S. 90-88. Such published notice shall include a statement of the time, place and nature of the hearings on the proposal. Such hearings may not be commenced until after the expiration of at least 10 days from the date the general notice is published in accordance with this Rule. Such published notice shall include a reference to the legal authority under which the substance change is proposed, a statement of the proposed change and in the discretion of the commission a summary of the subjects and issues involved. In addition, notice of the proposed change and the date and place of the public hearing shall be sent by the commission to each registrant under the act.

(e) The commission may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed change the time during which such filings may be made.

(f) The commission shall before adding, deleting or rescheduling any substance and after gathering the necessary data make a scientific and medical evaluation as to whether such drug or other substances should be so controlled, transferred or removed as a controlled substance.

(g) The commission in making its determination whether to add, delete or reschedule a substance within Schedules I through VI of the North Carolina Controlled Substances Act must in accordance with G.S. 90-88(a) consider the following:

- (1) the actual or relative potential for abuse;
- (2) the scientific evidence of its pharmacological effect, if known;
- (3) the state of current scientific knowledge regarding the substance;
- (4) the history and current pattern of abuse;
- (5) the scope, duration and significance of abuse;
- (6) the risk to the public health;
- (7) the potential of the substance to produce psychic or physiological dependence liability; and
- (8) whether the substance is an immediate precursor of a substance already controlled under the North Carolina Controlled Substances Act.

*History Note:* Authority G.S. 90-88;  
Eff. June 30, 1978;  
Amended Eff. April 1, 1982;  
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.

#### **10A NCAC 26F .0118 BURDEN OF PROOF**

At any hearing the proponent for the addition, deletion or rescheduling of any substance within Schedules I through VI of the North Carolina Controlled Substances Act shall have the burden of proof.

*History Note:* Authority G.S. 90-88;

*Eff. June 30, 1978;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0119 TIME AND PLACE OF HEARING**

The hearing will commence at the place and time designated in the notice published in accordance with .0117(d) of this Subchapter, but, thereafter, it may be continued from day to day or recessed to a later day without notice other than announcement thereof by the presiding officer at the hearing.

*History Note: Authority G.S. 90-88; 150B-33;*  
*Eff. June 30, 1978;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0120 FINAL ORDER**

As soon as practicable after the hearing has been concluded, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall cause to be published its decision in the form of an order. This order shall specify the date on which it shall take effect which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall specify in the order its findings as to such conditions.

*History Note: Authority G.S. 90-88;*  
*Eff. June 30, 1978;*  
*Amended Eff. May 1, 1990;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0121 MEETING REQUIRED**

Pursuant to G.S. 90-88(d), any time a substance is added, deleted or rescheduled as a controlled substance, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall meet within 180 days and either agree or object to the change. In either case the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall adopt an order setting forth its decisions and the reasons therefor.

*History Note: Authority G.S. 90-88(d);*  
*Eff. June 30, 1978;*  
*Amended Eff. May 1, 1990;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*

#### **10A NCAC 26F .0122 HEARING PROCEDURE**

If the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services objects thereby precipitating a hearing under G.S. 90-88(d), the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall follow generally the procedures set forth in Rules .0114 through .0120 of this Subchapter.

*History Note: Authority G.S. 90-88(d);*  
*Eff. June 30, 1978;*  
*Amended Eff. May 1, 1990;*  
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*