Public Health Service Act (42 U.S.C. 247); or

(ii) Pursuant to paragraph (c) of this section.

(c) During the period May 12, 2023, through December 31, 2024, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in 21 CFR 1300.04(i), to a patient without having conducted an in-person medical evaluation of the patient if all of the conditions listed in paragraph (e) of this section are met.

(d) During the period November 12, 2023 through November 11, 2024, a DEA-registered practitioner is authorized to prescribe schedule II–V controlled substances via telemedicine, as defined in §1300.04(i) of this chapter, to a patient with whom the practitioner has a telemedicine relationship established via COVID–19 telemedicine prescribing flexibilities without having conducted an in-person medical evaluation of a patient if all of the conditions listed in paragraph (e) of this section are met.

(e) A practitioner is only authorized to issue prescriptions for controlled substances pursuant to paragraphs (c) or (d) of this section if all of the following conditions are met:

(1) The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice;

(2) The prescription is issued pursuant to a communication between a practitioner and a patient using an interactive telecommunications system referred to in 42 CFR 410.78(a)(3);

(3) The practitioner is:

(i) Authorized under their registration under 21 CFR 1301.13(e)(1)(iv) to prescribe the basic class of controlled substance specified on the prescription; or

(ii) Exempt from obtaining a registration to dispense controlled substances under 21 U.S.C. 822(d); and

(4) The prescription is consistent with all other requirements of 21 CFR part 1306.

[88 FR 30042, May 10, 2023, as amended at 88 FR 69882, Oct. 10, 2023]

EFFECTIVE DATE NOTE: At 88 FR 30042, May 10, 2023, §1307.41 was added, effective May 11, 2023 through Nov. 11, 2024. At 88 FR 69879, Oct. 10, 2023, the expiration date was extended to Dec. 31, 2024.

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

GENERAL INFORMATION

SCHEDULES

EXCLUDED NONNARCOTIC SUBSTANCES

EXEMPT CHEMICAL PREPARATIONS

EXCLUDED VETERINARY ANABOLIC STEROID IMPLANT PRODUCTS

EXEMPTED PRESCRIPTION PRODUCTS

EXEMPT ANABOLIC STEROID PRODUCTS

EXEMPT CANNABIS PLANT MATERIAL, AND PRODUCTS MADE THEREFROM, THAT CONTAIN TETRAHYDROCANNABINOLS

HEARINGS

AUTHORITY: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

SOURCE: 38 FR 8254, Mar. 30, 1973, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1308.01 Scope of this part.

Schedules of controlled substances established by section 202 of the Act (21 U.S.C. 812) and nonnarcotic substances, chemical preparations, veterinary anabolic steroid implant products, prescription products, anabolic steroid products, and cannabis plant material and products made therefrom that contain tetrahydrocannabinols excluded pursuant to section 201 of the Act (21 U.S.C. 811), as they are changed, updated, and republished from time to time, are set forth in this part.

[81 FR 97021, Dec. 30, 2016]

§ 1308.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13967, Mar. 24, 1997]

§ 1308.03 Administration Controlled Substances Code Number.

(a) Each controlled substance, or basic class thereof, has been assigned an ''Administration Controlled Substances Code Number'' for purposes of identification of the substances or class on certain Certificates of Registration issued by the Administration pursuant to §§ 1301.35 of this chapter and on certain order forms issued by the Administration pursuant to § 1305.05(d) of this chapter. Applicants for procurement and/or individual manufacturing quotas must include the appropriate code number on the application as required in §§ 1303.12(b) and 1303.22(a) of this chapter. Applicants for import and export permits must include the appropriate code number on the application as required in §§ 1312.12(a) and 1312.22(a) of this chapter. Authorized registrants who desire to import or export a controlled substance for which an import or export permit is not required must include the appropriate Administration Controlled Substances Code Number beneath or beside the name of each controlled substance listed on the DEA Form 236 (Controlled Substance Import/Export Declaration) which is executed for such importation or exportation as required in §§ 1312.18(c) and 1312.27(b) of this chapter.

(b) Except as stated in paragraph (a) of this section, no applicant or registrant is required to use the Administration Controlled Substances Code Number for any purpose.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 51 FR 15318, Apr. 23, 1986; 62 FR 13968, Mar. 24, 1997]

SCHEDULES

§ 1308.11 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, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Opiates.* Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation (for purposes of 3-methylthiofentanyl only, the term isomer includes the optical and geometric isomers):

(1) Acetyl-*alpha*-methylfentanyl (*N*-[1-(1-methyl-2-phenethyl)-4-piperidinyl]-*N*-phenylacetamide)	9815
(2) Acetylmethadol	9601
(3) Acetyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide)	9821

(43) 4-Fluoroisobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide; also known as *para*-fluoroisobutyryl fentanyl) 9824
(44) 2′-Fluoro *ortho*-fluorofentanyl (*N*-(1-(2-fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide; also known as 2′-fluoro 2-fluorofentanyl) 9855
(45) Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-2-carboxamide) 9834
(46) 3-Furanyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide) 9860
(47) Furethidine 9626
(48) Hydroxypethidine 9627
(49) Isobutyryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylisobutyramide) 9827
(50) Isotonitazene (*N*,*N*-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine) 9614
(51) Isovaleryl fentanyl (3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide) 9862
(52) Ketobemidone 9628
(53) Levomoramide 9629
(54) Levophenacylmorphan 9631
(55) *meta*-Fluorofentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide) 9857
(56) *meta*-Fluoroisobutyryl fentanyl (*N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide) 9858
(57) Methoxyacetyl fentanyl (2-methoxy-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide) 9825
(58) 4′-Methyl acetyl fentanyl (*N*-(1-(4-methylphenethyl)piperidin-4-yl)-*N*-phenylacetamide) 9819
(59) 3-Methylfentanyl (*N*-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-*N*-phenylpropanamide) 9813
(60) 3-Methylthiofentanyl (*N*-[3-methyl-1-(2-thienylethyl)-4-piperidinyl]-*N*-phenylpropanamide) 9833
(61) Metonitazene (*N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine) 9757
(62) Morpheridine 9632
(63) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine) 9661
(64) MT–45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) 9560
(65) Noracymethadol 9633
(66) Norlevorphanol 9634
(67) Normethadone 9635
(68) Norpipanone 9636
(69) Ocfentanil (*N*-(2-fluorophenyl)-2-methoxy-*N*-(1-phenethylpiperidin-4-yl)acetamide) 9838
(70) *ortho*-Fluoroacryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)acrylamide) 9852
(71) *ortho*-Fluorobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide; also known as 2-fluorobutyryl fentanyl) 9846
(72) *ortho*-Fluorofentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide); also known as 2-fluorofentanyl) 9816
(73) *ortho*-Fluorofuranyl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9863
(74) *ortho*-Fluoroisobutyryl fentanyl (*N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide) 9853
(75) *ortho*-Methyl acetylfentanyl (*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl acetylfentanyl) 9848

(76) *ortho*-Methyl methoxyacetyl fentanyl (2-methoxy-*N*-(2-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide; also known as 2-methyl methoxyacetyl fentanyl) 9820
(77) *para*-Chloroisobutyryl fentanyl (*N*-(4-chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide) 9826
(78) *para*-Fluorobutyryl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide) 9823
(79) *para*-Fluorofentanyl (*N*-(4-fluorophenyl)-*N*-[1-(2-phenylethyl)-4-piperidinyl]propanamide) 9812
(80) *para*-Fluoro furanyl fentanyl (*N*-(4-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide) 9854
(81) *para*-Methoxybutyryl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide) 9837
(82) *para*-Methoxyfuranyl fentanyl (*N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide 9859
(83) *para*-Methylcyclopropyl fentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide) 9865
(84) *para*-Methylfentanyl (*N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide; also known as 4-methylfentanyl) 9817
(85) PEPAP (1-(2-phenylethyl)-4-phenyl-4-acetoxypiperidine) 9663
(86) Phenadoxone 9637
(87) Phenampromide 9638
(88) Phenomorphan 9647
(89) Phenoperidine 9641
(90) Phenyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbenzamide; also known as benzoyl fentanyl) 9841
(91) Piritramide 9642
(92) Proheptazine 9643
(93) Properidine 9644
(94) Propiram 9649
(95) Racemoramide 9645
(96) Tetrahydrofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenyltetrahydrofuran-2-carboxamide) 9843
(97) Thiofentanyl (*N*-phenyl-*N*-[1-(2-thienyl)ethyl-4-piperidinyl]propanamide) 9835
(98) Thiofuranyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide; also known as 2-thiofuranyl fentanyl; thiophene fentanyl) 9839
(99) Tilidine 9750
(100) Trimeperidine 9646
(101) U–47700 (3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide) 9547
(102) Valeryl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylpentanamide) 9840
(103) Zipeprol (1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol) 9873

(c) *Opium derivatives.* Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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:

(1) Acetorphine 9319
(2) Acetyldihydrocodeine 9051
(3) Benzylmorphine 9052
(4) Codeine methylbromide 9070
(5) Codeine-N-Oxide 9053
(6) Cyprenorphine 9054
(7) Desomorphine 9055
(8) Dihydromorphine 9145
(9) Drotebanol 9335
(10) Etorphine (except hydrochloride salt) 9056
(11) Heroin 9200
(12) Hydromorphinol 9301

(13) Methyldesorphine 9302
(14) Methyldihydromorphine 9304
(15) Morphine methylbromide .. 9305
(16) Morphine methylsulfonate 9306
(17) Morphine-N-Oxide 9307
(18) Myrophine 9308
(19) Nicocodeine 9309
(20) Nicomorphine 9312
(21) Normorphine 9313
(22) Pholcodine 9314
(23) Thebacon 9315

(d) *Hallucinogenic substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this paragraph only, the term ''isomer'' includes the optical, position and geometric isomers):

(1) Alpha-ethyltryptamine 7249
Some trade or other names: etryptamine; Monase; α-ethyl-1H-indole-3-ethanamine; 3-(2-aminobutyl) indole; α-ET; and AET.
(2) 4-bromo-2,5-dimethoxy-amphetamine 7391
Some trade or other names: 4-bromo-2,5-dimethoxy-α-methylphenethylamine; 4-bromo-2,5-DMA
(3) 4-Bromo-2,5-dimethoxyphenethylamine 7392
Some trade or other names: 2-(4-bromo-2,5-dimethoxyphenyl)-1-aminoethane; alpha-desmethyl DOB; 2C-B, Nexus.
(4) 2,5-dimethoxyamphetamine 7396
Some trade or other names: 2,5-dimethoxy-α-methylphenethylamine; 2,5-DMA
(5) 2,5-dimethoxy-4-ethylamphet-amine 7399
Some trade or other names: DOET
(6) 2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C–T–7) 7348
(7) 4-methoxyamphetamine 7411
Some trade or other names: 4-methoxy-α-methylphenethylamine; paramethoxyamphetamine, PMA
(8) 5-methoxy-3,4-methylenedioxy-amphetamine 7401
(9) 4-methyl-2,5-dimethoxy-amphetamine 7395
Some trade and other names: 4-methyl-2,5-dimethoxy-α-methylphenethylamine; ''DOM''; and ''STP''
(10) 3,4-methylenedioxy amphetamine 7400
(11) 3,4-methylenedioxymethamphetamine (MDMA) 7405
(12) 3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4(methylenedioxy)-phenethylamine, N-ethyl MDA, MDE, MDEA 7404
(13) N-hydroxy-3,4-methylenedioxyamphetamine (also known as N-hydroxy-alpha-methyl-3,4(methylenedioxy)-phenethylamine, and N-hydroxy MDA 7402
(14) 3,4,5-trimethoxy amphetamine 7390
(15) 5-methoxy-N,N-dimethyltryptamine Some trade or other names: 5-methoxy-3-[2-(dimethylamino)ethyl]indole; 5-MeO-DMT 7431
(16) Alpha-methyltryptamine (other name: AMT) 7432
(17) Bufotenine 7433
Some trade and other names: 3-(β-Dimethylaminoethyl)-5-hydroxyindole; 3-(2-dimethylaminoethyl)-5-indolol; N, N-dimethylserotonin; 5-hydroxy-N,N-dimethyltryptamine; mappine
(18) Diethyltryptamine 7434

Some trade and other names: N,N-Diethyltryptamine; DET

(19) Dimethyltryptamine 7435
Some trade or other names: DMT

(20) 5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT) 7439

(21) Ibogaine 7260
Some trade and other names: 7-Ethyl-6,6β,7,8,9,10,12,13-octahydro-2-methoxy-6,9-methano-5H-pyrido [1′, 2′:1,2] azepino [5,4-b] indole; Tabernanthe iboga

(22) Lysergic acid diethylamide 7315

(23) Marihuana 7360

(24) Mescaline 7381

(25) Parahexyl—7374; some trade or other names: 3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran; Synhexyl.

(26) Peyote 7415
Meaning all parts of the plant presently classified botanically as *Lophophora williamsii Lemaire*, whether growing or not, the seeds thereof, any extract from any part of such plant, and every compound, manufacture, salts, derivative, mixture, or preparation of such plant, its seeds or extracts

(Interprets 21 USC 812(c), Schedule I(c) (12))

(27) N-ethyl-3-piperidyl benzilate 7482

(28) N-methyl-3-piperidyl benzilate 7484

(29) Psilocybin 7437

(30) Psilocyn 7438

(31) Tetrahydrocannabinols 7370
(i) Meaning tetrahydrocannabinols, except as in paragraph (d)(31)(ii) of this section, naturally contained in a plant of the genus Cannabis (cannabis plant), as well as synthetic equivalents of the substances contained in the cannabis plant, or in the resinous extractives of such plant, and/or synthetic substances, derivatives, and their isomers with similar chemical structure and pharmacological activity to those substances contained in the plant, 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 of atomic positions covered.)

(ii) Tetrahydrocannabinols does not include any material, compound, mixture, or preparation that falls within the definition of hemp set forth in 7 U.S.C. 1639*o*.

(32) Ethylamine analog of phencyclidine 7455
Some trade or other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl)ethylamine, N-(1-phenylcyclohexyl)ethylamine, cyclohexamine, PCE

(33) Pyrrolidine analog of phencyclidine 7458

Some trade or other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP

(34) Thiophene analog of phencyclidine 7470
Some trade or other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienylanalog of phencyclidine, TPCP, TCP

(35) 1-[1-(2-thienyl)cyclohexyl]pyrrolidine 7473
Some other names: TCPy

(36) 4-methylmethcathinone (Mephedrone) 1248

(37) 3,4-methylenedioxypyrovalerone (MDPV) 7535

(38) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C–E) 7509

(39) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C–D) 7508

(40) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C–C) 7519

(41) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C–I) 7518

(42) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–2) 7385

(43) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C–T–4) 7532

(44) 2-(2,5-Dimethoxyphenyl)ethanamine (2C–H) 7517

(45) 2-(2,5-Dimethoxy-4-nitrophenyl)ethanamine (2C–N) 7521

(46) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C–P) 7524

(47) 3,4-Methylenedioxy-N-methylcathinone (Methylone) 7540

(48) (1-pentyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (UR-144) ..... (7144)

(49) [1-(5-fluoro-pentyl)-1*H*-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)methanone (5-fluoro-UR-144, XLR11) ..... (7011)

(50) *N*-(1-adamantyl)-1-pentyl-1*H*-indazole-3-carboxamide (APINACA, AKB48) ..... (7048)

(51) quinolin-8-yl 1-pentyl-1*H*-indole-3-carboxylate (PB-22; QUPIC) ..... (7222)

(52) quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (5-fluoro-PB-22; 5F-PB-22) ..... (7225)

(53) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (AB-FUBINACA) ..... (7012)

(54) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (ADB-PINACA) ..... (7035)

(55) 2-(4-iodo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25I-NBOMe, 2C-I-NBOMe) ..... (7538)

(56) 2-(4-chloro-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25C-NBOMe, 2C-C-NBOMe) ... (7537)

(57) 2-(4-bromo-2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine (25B-NBOMe, 2C-B-NBOMe) ... (7536)

(58) Marihuana Extract 7350
Meaning an extract containing one or more cannabinoids that has been derived from any plant of the genus Cannabis, containing greater than 0.3% delta-9-tetrahydrocannabinol on a dry weight basis, other than the separated resin (whether crude or purified) obtained from the plant.

(59) 4-methyl-*N*-ethylcathinone (4-MEC) ..... (1249)

(60) 4-methyl-*alpha*-pyrrolidinopropiophenone (4-MePPP) ..... (7498)

(61) *alpha*-pyrrolidinopentiophenone (α-PVP) ..... (7545)

(62) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)butan-1-one (butylone, bk-MBDB) ..... (7541)

(63) 2-(methylamino)-1-phenylpentan-1-one (pentedrone) ..... (1246)
(64) 1-(1,3-benzodioxol-5-yl)-2-(methylamino)pentan-1-one (pentylone, bk-MBDP) ..... (7542)
(65) 4-fluoro-*N*-methylcathinone (4-FMC; flephedrone) ..... (1238)
(66) 3-fluoro-*N*-methylcathinone (3-FMC) ..... (1233)
(67) 1-(naphthalen-2-yl)-2-(pyrrolidin-1-yl)pentan-1-one (naphyrone) ..... (1258)
(68) *alpha*-pyrrolidinobutiophenone (α-PBP) ..... (7546)
(69) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (AB-CHMINACA) ..... (7031)
(70) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide (AB-PINACA) ..... (7023)
(71) [1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl)methanone (THJ-2201) ..... (7024)
(72) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide (MAB-CHMINACA; ADB-CHMINACA) ..... (7032)
(73) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: 5F-ADB; 5F-MDMB-PINACA) 7034
(74) methyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate (Other names: 5F-AMB) 7033
(75) *N*-(adamantan-1-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (Other names: 5F-APINACA, 5F-AKB48) 7049
(76) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (Other names: ADB-FUBINACA) 7010
(77) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-CHMICA, MMB-CHMINACA) 7042
(78) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other names: MDMB-FUBINACA) ... 7020
(79) methyl 2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamido)-3-methylbutanoate, (FUB–AMB, MMB–FUBINACA, AMB–FUBINACA) ..... (7021)
(80) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one (ethylone) 7547
(81) Naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (Other names: NM2201; CBL2201) 7221
(82) *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (Other name: 5F-AB-PINACA) 7025
(83) 1-(4-cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (Other names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL BINACA; CUMYL-4CN-BINACA; SGT-78) 7089
(84) methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (Other names: MMB-CHMICA; AMB-CHMICA) 7044
(85) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-b]pyridine-3-carboxamide (Other name: 5F-CUMYL-P7AICA) 7085
(86) *N*-ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one) 7543
(87) methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (4F–MDMB–BINACA, 4F–MDMB–BUTINACA) 7043

(88) 1-(4-methoxyphenyl)-*N*-methylpropan-2-amine (other names: *para*-methoxymethamphetamine, PMMA) ..... (1245)
(89) ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA) 7036
(90) methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: 5F-MDMB-PICA; 5F-MDMB-2201) 7041
(91) *N*-(adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (other names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)) 7047
(92) 1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA; SGT-25) 7083
(93) (1-(4-fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (other name: FUB-144) 7014
(94) *N*-Ethylhexedrone (Other names: α-ethylaminohexanophenone; 2-(ethylamino)-1-phenylhexan-1-one) 7246
(95) *alpha*-Pyrrolidinohexanophenone (Other names: α-PHP; α-pyrrolidinohexanophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one) 7544
(96) 4-Methyl-*alpha*-ethylaminopentiophenone (Other names: 4-MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one) 7245
(97) 4′-Methyl-*alpha*-pyrrolidinohexiophenone (Other names: MPHP; 4′-methyl-*alpha*-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one) 7446
(98) *alpha*-Pyrrolidinoheptaphenone (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one) 7548
(99) 4′-Chloro-*alpha*-pyrrolidinovalerophenone (Other names: 4-chloro-α-PVP; 4′-chloro-α-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one) 7443
(100) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexan-1-one (methoxetamine, MXE) ... 7286
(101) 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one (other names: eutylone; bk-EBDB) 7549
(102) *N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1*H*-indazole-3-carboxamide (other name: ADB–BUTINACA) 7027
(103) 4-methyl-1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one (other names: α-PiHP; *alpha*-PiHP) 7551
(104) 2-(methylamino)-1-(3-methylphenyl)propan-1-one (other names: 3–MMC; 3-methylmethcathinone) 1259

(e) *Depressants.* Unless specifically excepted 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, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) gamma-hydroxybutyric acid (some other names include GHB; gamma-hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate) 2010
(2) Mecloqualone 2572
(3) Methaqualone 2565

(f) *Stimulants.* Unless specifically excepted 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:

(1) Amineptine (7-[(10,11-dihydro-5*H*-dibenzo[*a*,*d*]cyclohepten-5-yl)amino]heptanoic acid) 1219
(2) Aminorex (Some other names: aminoxaphen; 2-amino-5-phenyl-2-oxazoline; or 4,5-dihydro-5-phenly-2-oxazolamine) 1585
(3) N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine) 7493
(4) Cathinone 1235
Some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone
(5) 4,4′-Dimethylaminorex (4,4′-DMAR; 4,5-dihydro-4-methyl-5-(4-methylphenyl)-2-oxazolamine; 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine) 1595
(6) Fenethylline 1503
(7) Mesocarb (*N*-phenyl-*N′*-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate) 1227
(8) Methcathinone (Some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-*N*-methylaminopropiophenone; monomethylpropion; ephedrone; *N*-methylcathinone; methylcathinone; AL–464; AL–422; AL–463 and UR1432), its salts, optical isomers and salts of optical isomers 1237
(9) Methiopropamine (*N*-methyl-1-(thiophen-2-yl)propan-2-amine) 1478
(10) (±)*cis*-4-methylaminorex ((±)*cis*-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine) 1590
(11) N-ethylamphetamine 1475
(12) *N*,*N*-dimethylamphetamine (also known as *N*,*N*-alpha-trimethyl-benzeneethanamine; *N*,*N*-alpha-trimethylphenethylamine) 1480

(g) *Cannabimimetic agents.* Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP–47,497) 7297
(2) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP–47,497 C8-homolog) 7298
(3) 1-pentyl-3-(1-naphthoyl)indole (JWH–018 and AM678) 7118
(4) 1-butyl-3-(1-naphthoyl)indole (JWH–073) 7173
(5) 1-hexyl-3-(1-naphthoyl)indole (JWH–019) 7019
(6) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH–200) 7200
(7) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH–250) 6250
(8) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH–081) 7081
(9) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH–122) 7122
(10) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH–398) 7398
(11) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201) 7201
(12) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694) ... 7694
(13) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR–19 and RCS–4) 7104
(14) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole 7008 (SR–18 and RCS–8) 7008
(15) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH–203) 7203

(h) *Temporary listing of substances subject to emergency scheduling.* Any material, compound, mixture or preparation which contains any quantity of the following substances:

(1)–(29) [Reserved].

(30) Fentanyl-related substances, their isomers, esters, ethers, salts and salts of isomers, esters and ethers 9850

(i) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], that is structurally related to fentanyl by one or more of the following modifications:

(A) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;

(B) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino or nitro groups;

(C) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;

(D) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or

(E) Replacement of the *N*-propionyl group by another acyl group.

(ii) This definition includes, but is not limited to, the following substances: (A)–(B) [Reserved]

(31)-(49) [Reserved].

(50) 2-(2-(4-butoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)-*N*,*N*-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: Butonitazene) 9751

(51) 2-(2-(4-ethoxybenzyl)-1*H*-benzimidazol-1-yl)-*N*,*N*-diethylethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: Etodesnitazene; etazene) 9765

(52) *N*,*N*-diethyl-2-(2-(4-fluorobenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: Flunitazene) 9756

(53) *N*,*N*-diethyl-2-(2-(4-methoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: Metodesnitazene) 9764

(54) [Reserved].

(55) 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1*H*-benzimidazole, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other names: *N*-pyrrolidino etonitazene; etonitazepyne) 9758

(56) *N*,*N*-diethyl-2-(5-nitro-2-(4-propoxybenzyl)-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts, and salts of isomers, esters and ethers (Other name: Protonitazene) 9759

(57) 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: etizolam) 2780

(58) 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flualprazolam) 2785

(59) 6-(2-chlorophenyl)-1-methyl-8-nitro-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: clonazolam) 2786

(60) 8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine, its salts, isomers, and salts of isomers (Other name: flubromazolam) 2788

(61) 7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-benzo[*e*][1,4]diazepin-2-one, its salts, isomers, and salts of isomers (Other name: diclazepam) 2789

(62) Methyl 3,3-dimethyl-2-(1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamido)butanoate, its optical and geometric isomers, salts and salts of isomers (Other name: MDMB–4en–PINACA) 7090
(63) Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 4F–MDMB–BUTICA; 4F–MDMB–BICA) 7091
(64) *N*-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-en-1-yl)-1*H*-indazole-3-carboxamide, its optical and geometric isomers, salts and salts of isomers (Other name: ADB–4en–PINACA) 7092
(65) 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one, its optical and geometric isomers, salts and salts of isomers (Other names: CUMYL–PEGACLONE; SGT–151) 7093
(66) Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate, its optical and geometric isomers, salts and salts of isomers (Other names: 5F–EDMB–PICA; 5F–EDMB–2201) 7094
(67) Methyl 2-(1-(4-fluorobenzyl)-1*H*-indole-3-carboxamido)-3-methyl butanoate, its optical and geometric isomers, salts and salts of isomers (Other name: MMB–FUBICA) 7095

[39 FR 22141, June 20, 1974]

EDITORIAL NOTES: For FEDERAL REGISTER citations affecting §1308.11, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

2.At 88 FR 13694, Mar. 6, 2022, §1308.11 was amended; however, the amendment could not be incorporated due to inaccurate amendatory instruction.

EFFECTIVE DATE NOTES:

1.At 83 FR 5191, Feb. 6, 2018, §1308.11 was amended by adding paragraph (h)(30), effective Feb. 6, 2018, through Feb. 6, 2020. Effective Feb. 6, 2020, Congress extended the effective period for paragraph (h)(30) until May 6, 2021, by Public Law 116–114. Effective May 4, 2021, Congress extended the effective period for paragraph (h)(30) until October 22, 2021, by Public Law 117-12. Effective Sept. 30, 2021, Congress extended the effective period for paragraph (h)(30) until Jan. 28, 2022, by Public Law 117-43. Effective Jan. 13, 2022, Congress extended the effective period for paragraph (h)(30) until Feb. 18, 2022, by Public Law 117-70. Effective Feb. 18, 2022, Congress extended the effective period for paragraph (h)(30) until Mar. 11, 2022, by Public Law 117-86. Effective Mar. 11, 2022, Congress extended the effective period for paragraph (h)(30) until Mar. 15, 2022 by Public Law 117-95. Effective Mar. 15, 2022, Congress extended the effective period for paragraph (h)(30) until Dec. 31, 2022 by Public Law No. 117-103. Effective Dec. 29, 2022, Congress extended the effective period for paragraph (h)(30) until Dec. 31, 2024 by Public Law No. 117-328.

2. At 87 FR 21561, Apr. 12, 2022, §1308.11 was amended by adding paragraphs (h)(50) through (h)(56), effective Apr. 12, 2022 through Apr. 12, 2024.

3. At 88 FR 48118, July 26, 2023, §1308.11 was amended by adding paragraphs (h)(57) through (h)(61), effective July 26, 2023 through July 26, 2025.

4. At 88 FR 86045, Dec. 12, 2023, §1308.11 was amended by adding pargaraphs (h)(62) through (h)(65), effective Dec. 12, 2023 through Dec. 12, 2025.

5. At 89 18795, Mar. 15, 2024, §1308.11 was amended by redesignating paragraphs (b)(59) through (b)(103) as paragraphs (b)(60) through (104) and adding a new (b)(59), effective Apr. 15, 2024. For the convenience of the user, the added text is set forth as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

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* *

(59) 2-Methyl AP–237 (1-(2-methyl-4-(3-phenylprop-2-en-1-yl)piperazin-1-yl)butan-1-one) 9664

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§ 1308.12 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, listed in this section. Each drug or substance has been assigned the Controlled Substances Code Number set forth opposite it.

(b) *Substances, vegetable origin or chemical synthesis.* Unless specifically excepted or unless listed in another schedule, any 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:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxegol, naloxone, 6β-naltrexol, naltrexone, and samidorphan, and their respective salts, but including the following:

(i) Codeine	9050
(ii) Dihydroetorphine	9334
(iii) Ethylmorphine	9190
(iv) Etorphine hydrochloride	9059
(v) Granulated opium	9640
(vi) Hydrocodone	9193
(vii) Hydromorphone	9150
(viii) Metopon	9260
(ix) Morphine	9300
(x) Noroxymorphone	9668
(xi) Opium extracts	9610
(xii) Opium fluid	9620
(xiii) Oripavine	9330
(xiv) Oxycodone	9143
(xv) Oxymorphone	9652
(xvi) Powdered opium	9639
(xvii) Raw opium	9600
(xviii) Thebaine	9333
(xix) Tincture of opium	9630

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in paragraph (b) (1) of this section, except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves (9040) and any salt, compound, derivative or preparation of coca leaves (including cocaine (9041) and ecgonine (9180) and their salts, isomers, derivatives and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include:

(i) Decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine;

(ii) [^{123}I]ioflupane; or

(iii) [^{18}F]FP–CIT.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid or powder form which contains the phenanthrene alkaloids of the opium poppy), 9670.

(c) *Opiates.* Unless specifically excepted or unless in another schedule any of the following opiates, including its isomers, esters, ethers, salts and salts of isomers, esters and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanil	9737
(2) Alphaprodine	9010
(3) Anileridine	9020
(4) Bezitramide	9800
(5) Bulk dextropropoxyphene (non-dosage forms)	9273
(6) Carfentanil	9743
(7) Dihydrocodeine	9120
(8) Diphenoxylate	9170
(9) Fentanyl	9801
(10) Isomethadone	9226
(11) Levo-alphacetylmethadol [Some other names: levo-alpha-acetylmethadol, levomethadyl acetate, LAAM]	9648
(12) Levomethorphan	9210
(13) Levorphanol	9220
(14) Metazocine	9240
(15) Methadone	9250
(16) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane	9254
(17) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid	9802

(18) Oliceridine (*N*-[(3-methoxythiophen-2-yl)methyl]({2-[(9*R*)-9-(pyridin-2-yl)-6-oxaspiro[4.5]decan-9-yl]ethyl})amine) 9245
(19) Pethidine (meperidine) 9230
(20) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine 9232
(21) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate 9233
(22) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid 9234
(23) Phenazocine 9715
(24) Piminodine 9730
(25) Racemethorphan 9732
(26) Racemorphan 9733
(27) Remifentanil 9739
(28) Sufentanil 9740
(29) Tapentadol 9780
(30) Thiafentanil 9729

(d) *Stimulants.* Unless specifically excepted 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:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers 1100
(2) Methamphetamine, its salts, isomers, and salts of its isomers 1105
(3) Phenmetrazine and its salts 1631
(4) Methylphenidate 1724
(5) Lisdexamfetamine, its salts, isomers, and salts of its isomers ..... 1205.

(e) *Depressants.* Unless specifically excepted 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, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital 2125
(2) Glutethimide 2550
(3) Pentobarbital 2270
(4) Phencyclidine 7471
(5) Secobarbital 2315

(f) *Hallucinogenic substances.*

(1) Nabilone 7379
[Another name for nabilone: (±)-*trans*-3-(1,1-dimethylheptyl)-6,6a,7,8,10,10a-hexahydro-1-hydroxy-6,6-dimethyl-9H-dibenzo[b,d]pyran-9-one]
(2) Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration ..... (7365)

(g) *Immediate precursors.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(i) Phenylacetone 8501
Some trade or other names: phenyl-2-propanone; P2P; benzyl methyl ketone; methyl benzyl ketone;

(2) Immediate precursors to phencyclidine (PCP):

(i) 1-phenylcyclohexylamine 7460
(ii) 1-piperidinocyclohexanecarbonitrile (PCC) 8603

(3) Immediate precursor to fentanyl:

(i) 4-anilino-N-phenethylpiperidine (ANPP) ... 8333
(ii) *N*-phenyl-*N*-(piperidin-4-yl)propionamide (norfentanyl) 8366

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.12, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 1308.13 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, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Stimulants.* Unless specifically excepted 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 (whether optical, positional, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under §1308.32, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances 1405
(2) Benzphetamine 1228
(3) Chlorphentermine 1645
(4) Clortermine 1647
(5) Phendimetrazine 1615

(c) *Depressants.* Unless specifically excepted 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:

(1) Any compound, mixture or preparation containing:
(i) Amobarbital 2126
(ii) Secobarbital 2316
(iii) Pentobarbital 2271
or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.
(2) Any suppository dosage form containing:
(i) Amobarbital 2126
(ii) Secobarbital 2316
(iii) Pentobarbital 2271
or any salt of any of these drugs and approved by the Food and Drug Administration for marketing only as a suppository.
(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof 2100
(4) Chlorhexadol 2510
(5) Embutramide 2020
(6) Any drug product containing gamma hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act 2012
(7) Ketamine, its salts, isomers, and salts of isomers 7285
[Some other names for ketamine: (±)-2-(2-chlorophenyl)-2-(methylamino)-cyclohexanone]
(8) Lysergic acid 7300
(9) Lysergic acid amide 7310
(10) Methyprylon 2575
(11) Perampanel, and its salts, isomers, and salts of isomers .. 2261
(12) Sulfondiethylmethane 2600
(13) Sulfonethylmethane 2605
(14) Sulfonmethane 2610
(15) Tiletamine and zolazepam or any salt thereof 7295
Some trade or other names for a tiletamine-zolazepam combination product:
Telazol.
Some trade or other names for tiletamine:
2-(ethylamino)-2-(2-thienyl)-cyclohexanone.
Some trade or other names for zolazepam:
4-(2-fluorophenyl)-6,8-dihydro-1,3,8-trimethylpyrazolo-[3,4-*e*] [1,4]-diazepin-7(1*H*)-one, flupyrazapon.

(d) Nalorphine 9400.

(e) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule:

(1) Any material, 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 below:

(i) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium 9803

(ii) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ... 9804

(iii) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts 9807

(iv) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts 9808

(v) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ... 9809

(vi) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts ... 9810

(2) Any material, compound, mixture, or preparation containing any of the following narcotic drugs or their salts, as set forth below:

(i) Buprenorphine 9064

(ii) [Reserved] .....

(f) *Anabolic steroids.* Unless specifically excepted or unless listed in another schedule, any substance meeting the definition of anabolic steroid as set forth in §1300.01 of this chapter, including any material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers (4000):

(1) 5α-androstan-3,17-dione;

(2) 5α-androstan-3,6,17-trione;

(3) 1-androstenediol (3β,17β-dihydroxy-5α-androst-1-ene);

(4) 1-androstenediol (3α,17β-dihydroxy-5α-androst-1-ene);

(5) 4-androstenediol (3β,17β-dihydroxy-androst-4-ene);

(6) 5-androstenediol (3β,17β-dihydroxy-androst-5-ene);

(7) 1-androstenedione (5α-androst-1-en-3,17-dione);

(8) 4-androstenedione (androst-4-en-3,17-dione);

(9) 5-androstenedione (androst-5-en-3,17-dione);

(10) bolasterone (7α,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(11) boldenone (17β-hydroxyandrost-1,4-diene-3-one);

(12) boldione (androsta-1,4-diene-3,17-dione);

(13) 6-bromo-androsta-1,4-diene-3,17-dione;

(14) 6-bromo-androstan-3,17-dione;

(15) calusterone (7β,17α-dimethyl-17β-hydroxyandrost-4-en-3-one);

(16) 4-chloro-17α-methyl-androsta-1,4-diene-3,17β-diol;

(17) 4-chloro-17α-methyl-androst-4-ene-3β,17β-diol;

(18) 4-chloro-17α-methyl-17β-hydroxyandrost-4-en-3-one;

(19) 4-chloro-17α-methyl-17β-hydroxyandrost-4-ene-3,11-dione;

(20) clostebol (4-chloro-17β-hydroxyandrost-4-en-3-one);
(21) dehydrochloromethyltestosterone (4-chloro-17β-hydroxy-17α-methyl-androst-1,4-dien-3-one);
(22) desoxymethyltestosterone (17α-methyl-5α-androst-2-en-17β-ol) (a.k.a. ''madol'');
(23) 4-dihydrotestosterone (17β-hydroxy-androstan-3-one);
(24) Δ1-dihydrotestosterone (a.k.a. ''1-testosterone'') (17β-hydroxy-5α-androst-1-en-3-one);
(25) 3β,17β-dihydroxy-5α-androstane;
(26) 3α,17β-dihydroxy-5α-androstane;
(27) 2α,17α-dimethyl-17β-hydroxy-5β-androstan-3-one;
(28) drostanolone (17β-hydroxy-2α-methyl-5α-androstan-3-one);
(29) 2α,3α-epithio-17α-methyl-5α-androstan-17β-ol;
(30) estra-4,9,11-triene-3,17-dione;
(31) 13β-ethyl-17β-hydroxygon-4-en-3-one;
(32) ethylestrenol (17α-ethyl-17β-hydroxyestr-4-ene);
(33) fluoxymesterone (9-fluoro-17α-methyl-11β,17β-dihydroxyandrost-4-en-3-one);
(34) formebolone (2-formyl-17α-methyl-11α,17β-dihydroxyandrost-1,4-dien-3-one);
(35) furazabol (17α-methyl-17β-hydroxyandrostano[2,3-c]furazan);
(36) [3,2-c]furazan-5α-androstan-17β-ol;
(37) 18a-homo-3-hydroxy-estra-2,5(10)-dien-17-one;
(38) 4-hydroxy-19-nortestosterone (4,17β-dihydroxy-estr-4-en-3-one);
(39) 4-hydroxy-androst-4-ene-3,17-dione;
(40) 17β-hydroxy-androstano[2,3-d]isoxazole;
(41) 17β-hydroxy-androstano[3,2-c]isoxazole;
(42) 3β-hydroxy-estra-4,9,11-trien-17-one;
(43) 4-hydroxytestosterone (4,17β-dihydroxy-androst-4-en-3-one);
(44) mestanolone (17α-methyl-17β-hydroxy-5α-androstan-3-one);
(45) mesterolone (1α-methyl-17β-hydroxy-5α-androstan-3-one);
(46) methandienone (17α-methyl-17β-hydroxyandrost-1,4-dien-3-one);
(47) methandriol (17α-methyl-3β,17β-dihydroxyandrost-5-ene);
(48) methasterone (2α,17α-dimethyl-5α-androstan-17β-ol-3-one or 2α,17α-dimethyl-17β-hydroxy-5α-androstan-3-one);
(49) methenolone (1-methyl-17β-hydroxy-5α-androst-1-en-3-one);
(50) 17α-methyl-androsta-1,4-diene-3,17β-diol;
(51) 17α-methyl-5α-androstan-17β-ol;
(52) 17α-methyl-androstan-3-hydroxyimine-17β-ol;
(53) 6α-methyl-androst-4-ene-3,17-dione;
(54) 17α-methyl-androst-2-ene-3,17β-diol;
(55) 17α-methyl-3β,17β-dihydroxy-5α-androstane;
(56) 17α-methyl-3α,17β-dihydroxy-5α-androstane;
(57) 17α-methyl-3β,17β-dihydroxyandrost-4-ene;
(58) 17α-methyl-4-hydroxynandrolone (17α-methyl-4-hydroxy-17β-hydroxyestr-4-en-3-one);
(59) methyldienolone (17α-methyl-17β-hydroxyestra-4,9(10)-dien-3-one);
(60) 17α-methyl-Δ1-dihydrotestosterone (17β-hydroxy-17α-methyl-5α-androst-1-en-3-one) (a.k.a. ''17-α-methyl-1-testosterone'');
(61) methyltestosterone (17α-methyl-17β-hydroxyandrost-4-en-3-one);
(62) methyltrienolone (17α-methyl-17β-hydroxyestra-4,9,11-trien-3-one);
(63) mibolerone (7α,17α-dimethyl-17β-hydroxyestr-4-en-3-one);
(64) nandrolone (17β-hydroxyestr-4-en-3-one);
(65) 19-nor-4-androstenediol (3β,17β-dihydroxyestr-4-ene);
(66) 19-nor-4-androstenediol (3α,17β-dihydroxyestr-4-ene);
(67) 19-nor-5-androstenediol (3β,17β-dihydroxyestr-5-ene);
(68) 19-nor-5-androstenediol (3α,17β-dihydroxyestr-5-ene);
(69) 19-nor-4,9(10)-androstadienedione (estra-4,9(10)-diene-3,17-dione);
(70) 19-nor-4-androstenedione (estr-4-en-3,17-dione);
(71) 19-nor-5-androstenedione (estr-5-en-3,17-dione);
(72) norbolethone (13β,17α-diethyl-17β-hydroxygon-4-en-3-one);
(73) norclostebol (4-chloro-17β-hydroxyestr-4-en-3-one);
(74) norethandrolone (17α-ethyl-17β-hydroxyestr-4-en-3-one);

(75) normethandrolone (17α-methyl-17β-hydroxyestr-4-en-3-one);
(76) oxandrolone (17α-methyl-17β-hydroxy-2-oxa-5α-androstan-3-one);
(77) oxymesterone (17α-methyl-4,17β-dihydroxyandrost-4-en-3-one);
(78) oxymetholone (17α-methyl-2-hydroxymethylene-17β-hydroxy-5α-androstan-3-one);
(79) prostanozol (17β-hydroxy-5α-androstano[3,2-c]pyrazole or [3,2-c]pyrazole-5α-androstan-17β-ol);
(80) [3,2-c]pyrazole-androst-4-en-17β-ol;
(81) stanozolol (17α-methyl-17β-hydroxy-5α-androst-2-eno[3,2-c]-pyrazole);
(82) stenbolone (17β-hydroxy-2-methyl-5α-androst-1-en-3-one);
(83) testolactone (13-hydroxy-3-oxo-13,17-secoandrosta-1,4-dien-17-oic acid lactone);
(84) testosterone (17β-hydroxyandrost-4-en-3-one);
(85) tetrahydrogestrinone (13β,17α-diethyl-17β-hydroxygon-4,9,11-trien-3-one); and
(86) trenbolone (17β-hydroxyestr-4,9,11-trien-3-one).

(g) *Hallucinogenic substances.* (1) Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration approved product—7369.

[Some other names for dronabinol: (6a*R-trans*)-6a,7,8,10a-tetrahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo [*b,d*]pyran-1-ol] or (-)-delta-9-(*trans*)-tetrahydrocannabinol]

(2) [Reserved]

[39 FR 22142, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 1308.13, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 1308.14 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, listed in this section. Each drug or substance has been assigned the DEA Controlled Substances Code Number set forth opposite it.

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, 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 below:

(1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit	9167
(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane)	9278
(3) 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers and salts of these isomers (including tramadol)	9752

(c) *Depressants.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following 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:

(1) Alfaxalone	2731
(2) Alprazolam	2882
(3) Barbital	2145
(4) Brexanolone	2400
(5) Bromazepam	2748
(6) Camazepam	2749
(7) Carisoprodol	8192
(8) Chloral betaine	2460
(9) Chloral hydrate	2465
(10) Chlordiazepoxide	2744
(11) Clobazam	2751
(12) Clonazepam	2737
(13) Clorazepate	2768
(14) Clotiazepam	2752
(15) Cloxazolam	2753
(16) Daridorexant	2410
(17) Delorazepam	2754
(18) Diazepam	2765
(19) Dichloralphenazone	2467
(20) Estazolam	2756
(21) Ethchlorvynol	2540
(22) Ethinamate	2545
(23) Ethyl loflazepate	2758
(24) Fludiazepam	2759
(25) Flunitrazepam	2763
(26) Flurazepam	2767
(27) Fospropofol	2138
(28) Halazepam	2762
(29) Haloxazolam	2771

(30) Ketazolam 2772
(31) Lemborexant 2245
(32) Loprazolam 2773
(33) Lorazepam 2885
(34) Lormetazepam 2774
(35) Mebutamate 2800
(36) Medazepam 2836
(37) Meprobamate 2820
(38) Methohexital 2264
(39) Methylphenobarbital (mephobarbital) 2250
(40) Midazolam 2884
(41) Nimetazepam 2837
(42) Nitrazepam 2834
(43) Nordiazepam 2838
(44) Oxazepam 2835
(45) Oxazolam 2839
(46) Paraldehyde 2585
(47) Petrichloral 2591
(48) Phenobarbital 2285
(49) Pinazepam 2883
(50) Prazepam 2764
(51) Quazepam 2881
(52) Remimazolam 2846
(53) Suvorexant 2223
(54) Temazepam 2925
(55) Tetrazepam 2886
(56) Triazolam 2887
(57) Zaleplon 2781
(58) Zolpidem 2783
(59) Zopiclone 2784
(60) Zuranolone 2420

(d) [Reserved]

(e) *Lorcaserin.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of such isomers, whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Lorcaserin 1625

(f) *Stimulants.* Unless specifically excepted 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:

(1) Cathine ((+)-norpseudoephedrine) 1230
(2) Diethylpropion 1610
(3) Fencamfamin 1760
(4) Fenproporex 1575
(5) Mazindol 1605
(6) Mefenorex 1580
(7)Modafinil 1680
(8) Pemoline (including organometallic complexes and chelates thereof) 1530
(9) Phentermine 1640
(10) Pipradrol 1750
(11) Serdexmethylphenidate 1729
(12) Sibutramine 1675
(13) Solriamfetol (2-amino-3-phenylpropyl carbamate; benzenepropanol, beta-amino-, carbamate (ester)) 1650
(14) SPA ((-)-1-dimethylamino-1,2-diphenylethane) 1635

(g) *Other substances.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances, including its salts:

(1) Pentazocine 9709
(2) Butorphanol (including its optical isomers) 9720
(3) Eluxadoline (5-[[[(*2S*)-2-amino-3-[4-aminocarbonyl)-2,6-dimethylphenyl]-1-oxopropyl][(*1S*)-1-(4-phenyl-1*H*-imidazol-2-yl)ethyl]amino]methyl]-2-methoxybenzoic acid) (including its optical isomers) and its salts, isomers, and salts of isomers (9725)..

[39 FR 22143, June 20, 1974]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1308.14, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

§ 1308.15 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, listed in this section.

(b) *Narcotic drugs.* Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts, as set forth below:

(1) [Reserved]

(2) [Reserved]

(c) *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 below, which shall include one or more nonnarcotic 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 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(d) *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:

(1) Pyrovalerone ..... 1485.
(2) [Reserved].

(e) *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) Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB–34714; Briviact) (including its salts) 2710
(2) Cenobamate ([(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2*H*-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alpha*R*)-; carbamic acid (*R*)-(+)-1-(2-chlorophenyl)-2-(2*H*-tetrazol-2-yl)ethyl ester) 2720
(3) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester] 2779
(4) Ganaxolone (3α-hydroxy-3β-methyl-5α-pregnan-20-one) 2401
(5) Lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide] 2746
(6) Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide] 2790
(7) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] 2782

[39 FR 22143, June 20, 1974, as amended at 43 FR 38383, Aug. 28, 1978; 44 FR 40888, July 13, 1979; 47 FR 49841, Nov. 3, 1982; 50 FR 8108, Feb. 28, 1985; 52 FR 5952, Feb. 27, 1987; 53 FR 10870, Apr. 4, 1988; 56 FR 61372, Dec. 3, 1991; 67 FR 62370, Oct. 7, 2002; 70 FR 43635, July 28, 2005; 74 FR 23790, May 21, 2009; 76 FR 77899, Dec. 15, 2011; 81 FR 29491, May 12, 2016; 83 FR 48953, Sept 28, 2018; 85 FR 5562, Jan. 31, 2020; 85 FR 13746, Mar. 10, 2020; 85 FR 51645, Aug. 21, 2020; 87 FR 32996, June 1, 2022]

EXCLUDED NONNARCOTIC SUBSTANCES

§ 1308.21 Application for exclusion of a nonnarcotic substance.

(a) Any person seeking to have any nonnarcotic drug that may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)), may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(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 of the substance for which exclusion is sought; and

(3) The complete quantitative composition of the substance.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section 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 paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Administrator may at any time revoke any exclusion granted pursuant to section 201(g) of the Act (21 U.S.C. 811(g)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

[38 FR 8254, Mar. 30, 1973, as amended at 70 FR 74657, Dec. 16, 2005; 75 FR 10678, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1308.22 Excluded substances.

The following nonnarcotic substances which may, under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301), be lawfully sold over the counter without a prescription, are excluded from all schedules pursuant to section 201(g)(1) of the Act (21 U.S.C. 811(g)(1)):

EXCLUDED NONNARCOTIC PRODUCTS

Company	Trade name	NDC code	Form	Controlled substance	(mg or mg/ml)
Aphena Pharma Solutions—New York, LLC.	Nasal Decongestant Inhaler/Vapor Inhaler.	.....	IN	Levmetamfetamine (l-Desoxyephedrine).	50.00
Bioline Laboratories	Theophed	00719–1945	TB	Phenobarbital	8.00
Goldline Laboratories	Guiaphed Elixir	00182–1377	EL	Phenobarbital	4.00
Goldline Laboratories	Tedrigen Tablets	00182–0134	TB	Phenobarbital	8.00
Hawthorne Products Inc	Choate's Leg Freeze	.....	LQ	Chloral hydrate	246.67
Parke-Davis & Co	Tedral	00071–0230	TB	Phenobarbital	8.00
Parke-Davis & Co	Tedral Elixir	00071–0242	EX	Phenobarbital	40.00
Parke-Davis & Co	Tedral S.A.	00071–0231	TB	Phenobarbital	8.00
Parke-Davis & Co	Tedral Suspension	00071–0237	SU	Phenobarbital	80.00
Parmed Pharmacy	Asma-Ese	00349–2018	TB	Phenobarbital	8.10
Procter & Gamble Co., The	Vicks VapoInhaler	37000–686–01	IN	Levmetamfetamine (*l*-Desoxyephedrine).	50.00
Rondex Labs	Azma-Aids	00367–3153	TB	Phenobarbital	8.00
Smith Kline Consumer	Benzedrex	49692–0928	IN	Propylhexedrine	250.00
Sterling Drug, Inc	Bronkolixir	00057–1004	EL	Phenobarbital	0.80
Sterling Drug, Inc	Bronkotabs	00057–1005	TB	Phenobarbital	8.00
White Hall Labs	Primatene (P-tablets)	00573–2940	TB	Phenobarbital	8.00

[38 FR 8255, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 41 FR 16553, Apr. 20, 1976; 41 FR 53477, Dec. 7, 1976; 46 FR 51603, Oct. 21, 1981; 47 FR 45867, Oct. 14, 1982; 54 FR 2100, Jan. 19, 1989; 55 FR 12162, Mar. 30, 1990; 62 FR 13968, Mar. 24, 1997; 74 FR 44283, Aug. 28, 2009; 80 FR 65634, 65637, Oct. 27, 2015; 81 FR 6453, Feb. 8, 2016]

EXEMPT CHEMICAL PREPARATIONS

§ 1308.23 Exemption of certain chemical preparations; application.

(a) The Administrator may, by regulation, exempt from the application of all or any part of the Act any chemical preparation or mixture containing one or more controlled substances listed in any schedule, which preparation or mixture is intended for laboratory, industrial, educational, or special research purposes and not for general administration to a human being or other animal, if the preparation or mixture either:

(1) Contains no narcotic controlled substance and is packaged in such a form or concentration that the packaged quantity does not present any significant potential for abuse (the type of packaging and the history of abuse of the same or similar preparations may be considered in determining the potential for abuse of the preparation or mixture); or

(2) Contains either a narcotic or nonnarcotic controlled substance and one or more adulterating or denaturing agents in such a manner, combination, quantity, proportion, or concentration, that the preparation or mixture does not present any potential for abuse. If the preparation or mixture contains a narcotic controlled substance, the preparation or mixture must be formulated in such a manner that it incorporates methods of denaturing or other means so that the preparation or mixture is not liable to be abused or have ill effects, if abused, and so that the narcotic substance cannot in practice be removed.

(b) Any person seeking to have any preparation or mixture containing a controlled substance and one or more noncontrolled substances exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(c) An application for an exemption under this section 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 qualitative and quantitative composition of the preparation or mixture (including all active and inactive ingredients and all controlled 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 part 1300 of this chapter, 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 the 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 subsection 402(a)(8) of the Act (21 U.S.C. 842(a) (8)) or any other law restricting public disclosure of information.

(d) The Administrator may require the applicant to submit such documents or written statements of fact relevant to the application as he deems necessary to determine whether the application should be granted.

(e) Within a reasonable period of time after the receipt of an application for an exemption under this section,

the Administrator shall notify the applicant of his acceptance or nonacceptance of his application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) or requested pursuant to paragraph (d) 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 (c) and (d) of this section. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(f) The Administrator may at any time revoke or modify any exemption granted pursuant to this section by following the procedures set forth in paragraph (e) of this section for handling an application for an exemption which has been accepted for filing. The Administrator may also modify or revoke the criteria by which exemptions are granted (and thereby modify or revoke all preparations and mixtures granted under the old criteria) and modify the scope of exemptions at any time.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 46 FR 28841, May 29, 1981; 62 FR 13968, Mar. 24, 1997; 75 FR 10678, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1308.24 Exempt chemical preparations.

(a) The chemical preparations and mixtures approved pursuant to § 1308.23 are exempt from application of sections 302, 303, 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 822–823, 825–829, 952–954) and § 1301.74 of this chapter, to the extent described in paragraphs (b) to (h) of this section. Substances set forth in paragraph (j) of this section shall be exempt from the application of sections 305, 306, 307, 308, 309, 1002, 1003 and 1004 of the Act (21 U.S.C. 825–829, 952–954) and §§ 1301.71–1301.73 and 1301.74 (a), (b), (d), (e) and (f) of this chapter to the extent as hereinafter may be provided.

(b) Registration and security: Any person who manufactures an exempt chemical preparation or mixture must be registered under the Act and comply with all relevant security requirements regarding controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to be registered under the Act to handle that preparation, and the preparation is not required to be stored in accordance with security requirements regarding controlled substances.

(c) Labeling: In lieu of the requirements set forth in part 1302 of this chapter, the label and the labeling of an exempt chemical preparation must be prominently marked with its full trade name or other description and the name of the manufacturer or supplier as set forth in paragraph (i) of this section, in such a way that the product can be readily identified as an exempt chemical preparation. The label and labeling must also include in a prominent manner the statement ''For industrial use only'' or ''For chemical use only'' or ''For in vitro use only—not for human or animal use'' or ''Diagnostic reagent—for professional use only'' or a comparable statement warning the person reading it that human or animal use is not intended. The symbol designating the schedule of

the controlled substance is not required on either the label or the labeling of the exempt chemical preparation, nor is it necessary to list all ingredients of the preparation.

(d) *Records and reports:* Any person who manufactures an exempt chemical preparation or mixture must keep complete and accurate records and file all reports required under part 1304 of this chapter regarding all controlled substances being used in the manufacturing process until the preparation or mixture is in the form described in paragraph (i) of this section. In lieu of records and reports required under part 1304 of this chapter regarding exempt chemical preparations, the manufacturer need only record the name, address, and registration number, if any, of each person to whom the manufacturer distributes any exempt chemical preparation. Each importer or exporter of an exempt narcotic chemical preparation must submit a semiannual report of the total quantity of each substance imported or exported in each calendar half-year within 30 days of the close of the period to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Any other person who handles an exempt chemical preparation after it is in the form described in paragraph (i) of this section is not required to maintain records or file reports.

(e) Quotas, order forms, prescriptions, import, export, and transshipment requirements: Once an exempt chemical preparation is in the form described in paragraph (i) of this section, the requirements regarding quotas, order forms, prescriptions, import permits and declarations, export permit and declarations, and transshipment and intransit permits and declarations do not apply. These requirements do apply, however, to any controlled substances used in manufacturing the exempt chemical preparation before it is in the form described in paragraph (i) of this section.

(f) Criminal penalties: No exemption granted pursuant to §1308.23 affects the criminal liability for illegal manufacture, distribution, or possession of controlled substances contained in the exempt chemical preparation. Distribution, possession, and use of an exempt chemical preparation are lawful for registrants and nonregistrants only as long as such distribution, possession, or use is intended for laboratory, industrial, or educational purposes and not for immediate or subsequent administration to a human being or other animal.

(g) Bulk materials: For materials exempted in bulk quantities, the Administrator may prescribe requirements other than those set forth in paragraphs (b) through (e) of this section on a case-by-case basis.

(h) Changes in chemical preparations: Any change in the quantitative or qualitative composition of the preparation or mixture after the date of application, or change in the trade name or other designation of the preparation or mixture, set forth in paragraph (i) of this section, requires a new application for exemption.

(i) A listing of exempt chemical preparations may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(j) The following substances are designated as exempt chemical preparations for the purposes set forth in this section.

(1) *Chloral.* When packaged in a sealed, oxygen-free environment, under nitrogen pressure, safeguarded against exposure to the air.

(2) *Emit*[R] *Phenobarbital Enzyme Reagent B.* In one liter quantities each with a 5 ml. retention sample for repackaging as an exempt chemical preparation only.

[38 FR 8255, Mar. 30, 1973]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §1308.24, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.govinfo.gov*.

EXCLUDED VETERINARY ANABOLIC STEROID IMPLANT PRODUCTS

§ 1308.25 Exclusion of a veterinary anabolic steroid implant product; application.

(a) Any person seeking to have any anabolic steroid product, 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, identified as being excluded from any schedule, pursuant to section 102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)), may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration . See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

(b) An application for any exclusion under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;

(2) The name of the product;

(3) The chemical structural formula or description for any anabolic steroid contained in the product;

(4) A complete description of dosage and quantitative composition of the dosage form;.

(5) The conditions of use including whether or not Federal law restricts this product to use by or on the order of a licensed veterinarian;

(6) A description of the delivery system in which the dosage form will be distributed with sufficient detail to identify the product (e.g. 20 cartridge brown plastic belt);

(7) The label and labeling of the immediate container and the commercial containers, if any, of the product;.

(8) The name and address of the manufacturer of the dosage form if different from that of the applicant; and

(9) Evidence that the product has been approved by the Secretary of Health and Human Services for administration through implant to cattle or other nonhuman species.

(c) Within a reasonable period of time after the receipt of an application for an exclusion under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefore. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (b) of this section. If the application is accepted for filing, the Administrator shall issue and have published in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(d) The Administrator may at any time revoke or modify any designation of excluded status granted pursuant to this section by following the procedures set forth in paragraph (c) of this section for handling an application for an exclusion which has been accepted for filing.

[56 FR 42936, Aug. 30, 1991, as amended at 75 FR 10679, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1308.26 Excluded veterinary anabolic steroid implant products.

(a) Products containing an anabolic steroid, that are expressly intended for administration through implants to cattle or other nonhuman species and which have been approved by the Secretary of Health and Human Services for such administration are excluded from all schedules pursuant to section

102(41)(B)(i) of the Act (21 U.S.C. 802(41)(B)(i)). A listing of the excluded products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) In accordance with section 102(41)(B)(ii) of the Act (21 U.S.C. 802(41)(B)(ii)) if any person prescribes, dispenses, or distributes a product listed in paragraph (a) of this section for human use, such person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of section 102(41)(A) of the Act (21 U.S.C. 802(41)(A)).

[56 FR 42936, Aug. 30, 1991, as amended at 57 FR 19534, May 7, 1992; 58 FR 15088, Mar. 19, 1993; 62 FR 13967, Mar. 24, 1997; 75 FR 10679, Mar. 9, 2010]

EXEMPTED PRESCRIPTION PRODUCTS

§ 1308.31 Application for exemption of a nonnarcotic prescription product.

(a) Any person seeking to have any compound, mixture, or preparation containing any nonnarcotic controlled substance listed in §1308.12(e), or in §1308.13(b) or (c), or in §1308.14, or in §1308.15, exempted from application of all or any part of the Act pursuant to section 201(g)(3)(A), of the Act (21 U.S.C. 811(g)(3)(A)) may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(b) An application for an exemption under this section 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 and/or physiological dependence liability (this must be done for each of the active ingredients separately and for the combination product).

(4) Details of synergisms 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 2 years.

(c) Within a reasonable period of time after the receipt of an application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or non-acceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (b) of this section 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 section. If accepted for filing, the Administrator shall publish in the FEDERAL REGISTER general notice of this proposed rulemaking in granting or denying the application. Such notice shall include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule granting or denying an exemption, and, in the discretion of the Administrator, a summary of the subjects and issues involved. The Administrator shall permit any interested person to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made. After consideration of the application and any comments on or objections to his proposed rulemaking, the Administrator shall issue and publish in the FEDERAL REGISTER his final order on the application, which shall set forth the findings of fact and conclusions of law upon which the order is based. 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 in the FEDERAL REGISTER unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall

specify in the order his findings as to such conditions.

(d) The Administrator may revoke any exemption granted pursuant to section 201(g)(3)(A) of the Act (21 U.S.C. 811(g)(3)(A)) by following the procedures set forth in paragraph (c) of this section for handling an application for an exemption which has been accepted for filing.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 44 FR 18968, Mar. 30, 1979; 52 FR 9803, Mar. 27, 1987; 75 FR 10679, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1308.32 Exempted prescription products.

The compounds, mixtures, or preparations that contain a nonnarcotic controlled substance listed in §1308.12(e) or in §1308.13(b) or (c) or in §1308.14 or in §1308.15 listed in the Table of Exempted Prescription Products have been exempted by the Administrator from the application of sections 302 through 305, 307 through 309, and 1002 through 1004 of the Act (21 U.S.C. 822–825, 827–829, and 952–954) and §§1301.13, 1301.22, and §§1301.71 through 1301.76 of this chapter for administrative purposes only. An exception to the above is that those products containing butalbital shall not be exempt from the requirement of 21 U.S.C. 952–954 concerning importation, exportation, transshipment and in-transit shipment of controlled substances. Any deviation from the quantitative composition of any of the listed drugs shall require a petition of exemption in order for the product to be exempted. A listing of the Exempted Prescription Products may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10679, Mar. 9, 2010]

EXEMPT ANABOLIC STEROID PRODUCTS

§ 1308.33 Exemption of certain anabolic steroid products; application.

(a) The Administrator, upon the recommendation of Secretary of Health and Human Services, may, by regulation, exempt from the application of all or any part of the Act any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter, which is intended for administration to a human being or animal, if, because of its concentration, preparation, formulation, or delivery system, it has no significant potential for abuse.

(b) Any person seeking to have any compound, mixture, or preparation containing an anabolic steroid as defined in part 1300 of this chapter exempted from the application of all or any part of the Act, pursuant to paragraph (a) of this section, may apply to the Drug and Chemical Evaluation Section, Diversion Control Division, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

(c) An application for an exemption under this section shall be submitted in triplicate and contain the following information:

(1) The name and address of the applicant;

(2) The name of the product;

(3) The chemical structural formula or description for any anabolic steroid contained in the product;

(4) The complete description of dosage and quantitative composition of the dosage form;

(5) A description of the delivery system, if applicable;

(6) The indications and conditions for use in which species, including whether or not this product is a prescription drug;

(7) Information to facilitate identification of the dosage form, such as shape, color, coating, and scoring;

(8) The label and labeling of the immediate container and the commercial containers, if any, of the product;

(9) The units in which the dosage form is ordinarily available; and

(10) The facts which the applicant believes justify:

(i) A determination that the product has no significant potential for abuse and

(ii) a granting of an exemption under this section.

(d) Within a reasonable period of time after the receipt of the application for an exemption under this section, the Administrator shall notify the applicant of his acceptance or nonacceptance of the application, and if not accepted, the reason therefor. The Administrator need not accept an application for filing if any of the requirements prescribed in paragraph (c) of this section is lacking or is not set forth so as to be readily understood. The applicant may amend the application to meet the requirements of paragraph (c) of this section. If accepted for filing, the Administrator will request from the Secretary for Health and Human Services his recommendation, as to whether such product which contains an anabolic steroid should be considered for exemption from certain portions of the Controlled Substances Act. On receipt of the recommendation of the Secretary, the Administrator shall make a determination as to whether the evidence submitted or otherwise available sufficiently establishes that the product possesses no significant potential for abuse. The Administrator shall issue and publish in the FEDERAL REGISTER his order on the application, which shall include a reference to the legal authority under which the order is issued, and the findings of fact and conclusions of law upon which the order is based. This order shall specify the date on which it will take effect. The Administrator shall permit any interested person to file written comments on or objections to the order within 60 days of the date of publication of his order in the FEDERAL REGISTER. If any such comments or objections raise significant issues regarding any finding of fact or conclusion of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend his original order as he determines appropriate.

(e) The Administrator may revoke any exemption granted pursuant to section 1903(a) of Public Law 101–647 by following the procedures set forth in paragraph (d) of this section for handling an application for an exemption which has been accepted for filing.

[56 FR 42936, Aug. 30, 1991; 57 FR 10815, Mar. 31, 1992, as amended at 62 FR 13968, Mar. 24, 1997; 70 FR 74657, Dec. 16, 2005; 75 FR 10679, Mar. 9, 2010; 81 FR 97021, Dec. 30, 2016]

§ 1308.34 Exempt anabolic steroid products.

The list of compounds, mixtures, or preparations that contain an anabolic steroid that have been exempted by the Administrator from application of sections 302 through 309 and 1002 through 1004 of the Act (21 U.S.C. 822–829 and 952–954) and §§ 1301.13, 1301.22, and 1301.71 through 1301.76 of this chapter for administrative purposes only may be obtained by submitting a written request to the Drug and Chemical Evaluation Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in § 1321.01 of this chapter for the current mailing address.

[75 FR 10679, Mar. 9, 2010]

EXEMPT CANNABIS PLANT MATERIAL, AND PRODUCTS MADE THEREFROM, THAT CONTAIN TETRAHYDROCANNABINOLS

§ 1308.35 Exemption of certain cannabis plant material, and products made therefrom, that contain tetrahydrocannabinols.

(a) Any processed plant material or animal feed mixture containing any amount of tetrahydrocannabinols (THC) that is both:

(1) Made from any portion of a plant of the genus Cannabis excluded from the definition of marijuana under the Act [i.e., the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination] and

(2) Not used, or intended for use, for human consumption, has been exempted by the Administrator from the application of the Act and this chapter.

(b) As used in this section, the following terms shall have the meanings specified:

(1) The term *processed plant material* means cannabis plant material that has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption.

(2) The term *animal feed mixture* means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).

(3) The term *used for human consumption* means either:

(i) Ingested orally or

(ii) Applied by any means such that THC enters the human body.

(4) The term *intended for use for human consumption* means any of the following:

(i) Designed by the manufacturer for human consumption;

(ii) Marketed for human consumption; or

(iii) Distributed, exported, or imported, with the intent that it be used for human consumption.

(c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to §1308.23, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

[66 FR 51544, Oct. 9, 2001]

HEARINGS

§ 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§1308.42–1308.51, and by §§1316.41–1316.67 of this chapter.

§ 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to §1308.43, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in part 1316 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1308.43 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. Petitions shall be in the following form:

_____ (Date)

Administrator, Drug Enforcement Administration _____ (Mailing Address)

Dear Sir: The undersigned _____ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

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

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the

amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (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) Within a reasonable period of time after the receipt of a petition, the Administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Administrator need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Administrator within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Administrator shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to whether such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Administrator shall be binding on the Administrator as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Administrator shall not control that drug or other substance.

(e) If the Administrator determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Administrator determines to initiate proceedings, he shall publish in the FEDERAL REGISTER general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the FEDERAL REGISTER. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

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

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13968, Mar. 24, 1997; 75 FR 10679, Mar. 9, 2010]

§1308.44 Request for hearing or appearance; waiver.

(a) Any interested person desiring a hearing on a proposed rulemaking, shall, within 30 days after the date of publication of notice of the proposed rulemaking in the FEDERAL REGISTER, file with the Administrator a written request for a hearing in the form prescribed in §1316.47 of this chapter.

(b) Any interested person desiring to participate in a hearing pursuant to §1308.41 shall, within 30 days after the date of publication of the notice of hearing in the FEDERAL REGISTER, file with the Administrator a written notice of his intention to participate in such hearing in the form prescribed in §1316.48 of this chapter. Any person filing a request for a hearing need not also file a notice of appearance; the request for a hearing shall be deemed to be a notice of appearance.

(c) Any interested person may, within the period permitted for filing a request for a hearing, file with the Administrator a waiver of an opportunity for a hearing or to participate in a hearing, together with a written statement regarding his position on the matters of fact and law involved in such hearing. Such statement, if admissible, shall be made a part of the record and shall be considered in light of the lack of opportunity for cross-examination in determining the weight to be attached to matters of fact asserted therein.

(d) If any interested person fails to file a request for a hearing; or if he so files and fails to appear at the hearing, he shall be deemed to have waived his opportunity for the hearing or to participate in the hearing, unless he shows good cause for such failure.

(e) If all interested persons waive or are deemed to waive their opportunity for the hearing or to participate in the hearing, the Administrator may cancel the hearing, if scheduled, and issue his final order pursuant to §1308.45 without a hearing.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13968, Mar. 24, 1997]

§1308.45 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. 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 in the FEDERAL REGISTER unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13968, Mar. 24, 1997]

§1308.46 Control required under international treaty.

Pursuant to section 201(d) of the Act (21 U.S.C. 811(d)), where control of a substance is required by U.S. obligations under international treaties, conventions, or protocols in effect on May 1, 1971, the Administrator shall issue and publish in the FEDERAL REGISTER an order controlling such substance under the schedule he deems most appropriate to carry out obligations. Issuance of such an order shall be without regard to the findings required by subsections 201(a) or 202(b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by §1308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811 (a) and (b)). An order controlling a substance shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13968, Mar. 24, 1997]

§1308.47 Control of immediate precursors.

Pursuant to section 201(e) of the Act (21 U.S.C. 811(e)), the Administrator may, without regard to the findings required by subsection 201(a) or 202 (b) of the Act (21 U.S.C. 811(a) or 812(b)) and without regard to the procedures prescribed by §1308.41 or subsections 201 (a) and (b) of the Act (21 U.S.C. 811(a) and (b)), issue and publish in the FEDERAL REGISTER an order controlling an immediate precursor. The order shall designate the schedule in which the immediate precursor is to be placed, which shall be the same schedule in

which the controlled substance of which it is an immediate precursor is placed or any other schedule with a higher numerical designation. An order controlling an immediate precursor shall become effective 30 days from the date of publication in the FEDERAL REGISTER, unless the Administrator finds that conditions of public health or safety necessitate an earlier effective date, in which event the Administrator shall specify in the order his findings as to such conditions.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated at 62 FR 13968, Mar. 24, 1997]

§ 1308.49 Temporary scheduling.

(a) Pursuant to 21 U.S.C. 811(h) and without regard to the requirements of 21 U.S.C. 811(b) relating to the scientific and medical evaluation of the Secretary of Health and Human Services, the Drug Enforcement Administration may place a substance into Schedule I on a temporary basis, if it determines that such action is necessary to avoid an imminent hazard to the public safety. An order issued under this section may not be effective before the expiration of 30 calendar days from:

(1) The date of publication by the Administration of a notice in the FEDERAL REGISTER of its intention to issue such order and the grounds upon which such order is to be issued; and

(2) The date the Administration has transmitted notification to the Secretary of Health and Human Services of the Administration's intention to issue such order.

(b) An order issued under this section will be vacated upon the conclusion of a subsequent rulemaking proceeding initiated under section 201(a) (21 U.S.C. 811(a)) with respect to such substance or at the end of two years from the effective date of the order scheduling the substance, except that during the pendency of proceedings under section 201(a) (21 U.S.C. 811(a)) with respect to the substance, the Administration may extend the temporary scheduling for up to one year.

[81 FR 97021, Dec. 30, 2016]

§ 1308.50 Temporary and permanent scheduling of recently emerged anabolic steroids.

(a) The Administrator may issue a temporary order adding a drug or other substance to the definition of anabolic steroids if the Administrator finds that—

(1) The drug or other substance satisfies the criteria for being considered an anabolic steroid under 21 U.S.C. 802(41) but is not listed in that section or by regulation of the Attorney General as being an anabolic steroid; and

(2) Adding such drug or other substance to the definition of anabolic steroids will assist in preventing abuse or misuse of the drug or other substance.

(b) An order issued under paragraph (a) of this section shall not take effect until 30 days after the date of the publication by the Administrator of a notice in the FEDERAL REGISTER of the intention to issue such order and the grounds upon which such order is to be issued. The order shall expire not later than 24 months after the date it becomes effective, except that the Administrator may, during the pendency of proceedings under paragraph (f) of this section, extend the temporary scheduling order for up to 6 months.

(c) The Administrator shall transmit notice of an order proposed to be issued under paragraph (a) of this section to the Secretary of Health and Human Services. In issuing an order under paragraph (a), the Administrator shall take into consideration any comments submitted by the Secretary in response to a notice transmitted pursuant to this paragraph (c).

(d) A temporary scheduling order issued under paragraph (a) of this section shall be vacated upon the issuance of a permanent scheduling order under paragraph (f) of this section.

(e) An order issued under paragraph (a) of this section is not subject to judicial review.

(f) The Administrator may, by rule, issue a permanent order adding a drug or other substance to the definition of anabolic steroids if such drug or other substance satisfies the criteria for being considered an anabolic steroid

under 21 U.S.C. 802(41). Such rulemaking may be commenced simultaneously with the issuance of the temporary order issued under paragraph (a) of this section.

[88 FR 50041, Aug. 1, 2023]

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

GENERAL INFORMATION

FEES FOR REGISTRATION AND REREGISTRATION

REQUIREMENTS FOR REGISTRATION

APPLICATION FOR REGISTRATION

ACTION ON APPLICATIONS FOR REGISTRATION: REVOCATION OR SUSPENSION OF REGISTRATION

HEARINGS

MODIFICATION, TRANSFER AND TERMINATION OF REGISTRATION

SECURITY REQUIREMENTS

AUTHORITY: 21 U.S.C. 802, 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 952, 953, 957, 958.

SOURCE: 60 FR 32454, June 22, 1995, unless otherwise noted.

GENERAL INFORMATION

§ 1309.01 Scope of part 1309.

Procedures governing the registration of manufacturers, distributors, importers and exporters of List I chemicals pursuant to Sections 102, 302, 303, 1007 and 1008 of the Act (21 U.S.C. 802, 822, 823, 957 and 958) are set forth generally by those sections and specifically by the sections of this part.

§ 1309.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1309.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10680, Mar. 9, 2010]