

§ 1308.15

21 CFR Ch. II (4–1–24 Edition)

(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-[[[(2*S*)-2-amino-3-[4-aminocarbonyl]-2,6-dimethylphenyl]-1-oxopropyl][(1*S*)-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 non-narcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone:

(1) Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

(2) Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

(3) Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

(4) Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

(5) Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(6) Not more than 0.5 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; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+)-1-(2-chlorophenyl)-2-(2H-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