

§ 1308.15

(2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane) 9278

(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) Alprazolam	2882
(2) Barbitol	2145
(3) Bromazepam	2748
(4) Camazepam	2749
(5) Chloral betaine	2460
(6) Chloral hydrate	2465
(7) Chlordiazepoxide	2744
(8) Clobazam	2751
(9) Clonazepam	2737
(10) Clorazepate	2768
(11) Clotiazepam	2752
(12) Cloxazolam	2753
(13) Delorazepam	2754
(14) Diazepam	2765
(15) Dichloralphenazone	2467
(16) Estazolam	2756
(17) Ethchlorvynol	2540
(18) Ethinamate	2545
(19) Ethyl loflazepate	2758
(20) Fludiazepam	2759
(21) Flunitrazepam	2763
(22) Flurazepam	2767
(23) Fospropofol	2138
(24) Halazepam	2762
(25) Haloxazolam	2771
(26) Ketazolam	2772
(27) Loprazolam	2773
(28) Lorazepam	2885
(29) Lormetazepam	2774
(30) Mebutamate	2800
(31) Medazepam	2836
(32) Meprobamate	2820
(33) Methohexital	2264
(34) Methylphenobarbital (mephobarbital)	2250
(35) Midazolam	2884
(36) Nimetazepam	2837
(37) Nitrazepam	2834
(38) Nordiazepam	2838
(39) Oxazepam	2835
(40) Oxazolam	2839
(41) Paraldehyde	2585
(42) Petrichloral	2591
(43) Phenobarbital	2285
(44) Pinazepam	2883
(45) Prazepam	2764
(46) Quazepam	2881
(47) Temazepam	2925
(48) Tetrazepam	2886
(49) Triazolam	2887
(50) Zaleplon	2781
(51) Zolpidem	2783
(52) Zopiclone	2784

(d) *Fenfluramine.* Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers,

21 CFR Ch. II (4-1-11 Edition)

whenever the existence of such salts, isomers, and salts of isomers is possible:

(1) Fenfluramine 1670

(e) *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) Sibutramine	1675
(12) SPA ((-)-1-dimethylamino- 1,2-diphenylethane)	1635

(f) *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

[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.fdsys.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]

(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) Pyrovalerone1485.
- (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) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide]—2746
- (2) 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]

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 Office of Diversion Control, 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