

## § 1308.21

## 21 CFR Ch. II (4–1–23 Edition)

(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.

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(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]