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1. [21 CFR 1308.15](#)

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21 CFR 1308.15

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Code of Federal Regulations > TITLE 21 -- FOOD AND DRUGS > CHAPTER II -- DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE > PART 1308 -- SCHEDULES OF CONTROLLED SUBSTANCES > SCHEDULES

§ 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) 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) Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester] -- 2779

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

(4) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] -- 2782

(f) Approved cannabidiol drugs. (1) A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl] -5-pentyl-1,3-benzenedio l) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols7367

(2)[Reserved]

Statutory Authority

[21 U.S.C. 811](#), 812, 871(b).

History

[\[39 FR 22143\]](#), 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 62354, 62370](#), Oct. 7, 2002; [70 FR 43633, 43635](#), July 28, 2005; [74 FR 23789, 23790](#), May 21, 2009; [76 FR 77895, 77899](#), Dec. 15, 2011; [81 FR 29487, 29491](#), May 12, 2016, as confirmed at [82 FR 13067, 13069](#), Mar. 9, 2017; [83 FR 48950, 48953](#), Sept. 28, 2018]

Annotations

Notes

[EFFECTIVE DATE NOTE:

[76 FR 77895, 77899](#), Dec. 15, 2011, amended paragraph (e), effective Dec. 15, 2011; [81 FR 29487, 29491](#), May 12, 2016, amended this section, effective May 12, 2016; [83 FR 48950, 48953](#), Sept. 28, 2018 added paragraph (f), effective Sept. 28, 2018.]

Case Notes

LexisNexis® Notes

Case Notes Applicable to Entire Part

[Part Note](#)

Research References & Practice Aids

NOTES APPLICABLE TO ENTIRE TITLE:

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Cross References: Food Safety and Inspection Services, Department of Agriculture: See Meat and Poultry Inspection, 9 CFR CHAPTER III.

Federal Trade Commission: See Commercial Practices, 16 CFR chapter I.

U.S. Customs Service, Department of the Treasury: See Customs Duties, 19 CFR chapter I.

Internal Revenue Service, Department of the Treasury: See Internal Revenue, 26 CFR chapter I.

Bureau of Alcohol, Tobacco, and Firearms, Department of the Treasury: See Alcohol, Tobacco Production and Firearms, 27 CFR chapter I.

NOTES APPLICABLE TO ENTIRE PART:

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 1308 Controlled Substances Schedules, see: [62 FR 29288, 29289, 51774, 51776 \(1997\)](#); [65 FR 3124](#), Jan. 20, 2000, as confirmed at 43690, 43694, July 14, 2000; [66 FR 51530](#), Oct. 9, 2001; [68 FR 1964](#), Jan. 15, 2003, suspended at [68 FR 35293](#), June 13, 2003, withdrawn at [68 FR 53677](#), Sept. 12, 2003; [68 FR 53289](#), Sept. 10, 2003; [71 FR 10835](#), Mar. 3, 2006, as confirmed at [71 FR 61876, 61877](#), Oct. 20, 2006; [71 FR 51996](#), Sept. 1, 2006, as confirmed at [73 FR 14178, 14179](#), Mar. 17, 2008; [77 FR 12201](#), Feb. 29, 2012; [77 FR 64032](#), Oct. 18, 2012; [80 FR 27854](#), May 15, 2015; [84 FR 16397](#), Apr. 19, 2019.]

[PUBLISHER'S NOTE: For Federal Register citations concerning Part 1308 Temporary rule, see: [83 FR 4411](#), Jan. 30, 2018.]

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