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1. *21 CFR 1308.13*
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21 CFR 1308.13

This document is current through the July 29, 2019 issue of the Federal Register. Title 3 is current through July 12, 2019.

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

§ 1308.13 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 [Some other names for ketamine: ([+/-])-2-(2-chlorophenyl) -2-(methylamine)-cyclohexanone]	7285
(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(1H)-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 1003 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 material, compound, mixture or preparation containing any quantity of the following substances, including its salts, esters and ethers:

(1) Anabolic steroids (see § 1300.01 of this chapter) -- 4000

(2)[Reserved]

(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]

Statutory Authority

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

History

[39 FR 22142, June 20, 1974, as amended at *41 FR 43401,* Oct. 1, 1976; *43 FR 3359,* Jan. 25, 1978; *44 FR 40888,* July 13, l979; *46 FR 52334,* Oct. 27, 1981; *51 FR 5320,* Feb. 13, 1986; *52 FR 2222,* Jan. 21, 1987; *52 FR 5952,* Feb. 27, 1987; *56 FR 5754,* Feb. 13, 1991; *56 FR 11932,* March 21, 1991; *62 FR 13938, 13968,* March 24, 1997; *64 FR 35928, 35930,* July 2, 1999; *64 FR 37673, 37675,* July 13, 1999; *65 FR 13235, 13238,* Mar. 13, 2000, as corrected at *65 FR 17440,* Apr. 3, 2000; *67 FR 62354, 62370,* Oct. 7, 2002; *70 FR 74653, 74657,* Dec. 16, 2005; *71 FR 51115, 51116,* Aug. 29, 2006; *77 FR 4228, 4236,* Jan. 27, 2012; *78 FR 72013, 72016,* Dec. 2, 2013; *79 FR 49661, 49682,* Aug. 22, 2014]

Annotations

Notes

[EFFECTIVE DATE NOTE:

78 FR 72013, 72016, Dec. 2, 2013, amended paragraph (c), effective Jan. 2, 2014; *79 FR 49661, 49682,* Aug. 22, 2014, removed paragraphs (e)(1)(iii) and (iv) and redesignated paragraphs (e)(1)(v) through (viii) as (e)(1)(iii) through (vi), effective Oct. 6, 2014.]

Case Notes

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Case Notes Applicable to Entire Part
Administrative Law : Judicial Review : Standards of Review : Rule Interpretation

Criminal Law & Procedure : Criminal Offenses : Controlled Substances : Substance Schedules : General Overview
Criminal Law & Procedure : Criminal Offenses : Controlled Substances : Substance Schedules : Miscellaneous Drugs
Criminal Law & Procedure : Criminal Offenses : Miscellaneous Offenses : Goods Smuggling : General Overview
Governments : Agriculture & Food : Federal Food, Drug & Cosmetic Act

Case Notes Applicable to Entire Part

Part Note

Administrative Law : Judicial Review : Standards of Review : Rule Interpretation

John Doe, Inc. v. Dea, 484 F.3d 561, 2007 U.S. App. LEXIS 9567 (DC Cir Apr. 27, 2007).

Overview: *Because the manufacturer could petition the DEA for its drug to be placed in Schedule III under 21 U.S.C.S. § 811(a), the court declined to eliminate a limitation on an already existing Schedule III category, effectively rescheduling the manufacturer's drug without it making the statutorily required showing under 21 U.S.C.S. § 812(b).*

- There is nothing in *21 C.F.R. § 1308.13(g)(1)* that is contrary to the Controlled Substances Act. Nor is the United States Drug Enforcement Administration's (DEA) interpretation limiting that specific provision to drugs with United States Food and Drug Administration (FDA) marketing approval plainly erroneous. It is inappropriately restrictive for the DEA to say that FDA approval is the only way to demonstrate a drug is safe and has currently accepted medical use. But it is completely different (and eminently reasonable) for the DEA to require an importer, relying on functional equivalency as the basis for a drug's safety and current acceptance for medical use, to demonstrate that its drug is actually equivalent. *Go To Headnote*

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- Dronabinol, the active ingredient in Marinol, has been assigned to Schedule I since Congress first enacted the Controlled Substances Act (CSA) in 1970. Pub. L. No. 91-513, § 202, sched. I P (c)(17), 84 Stat. 1236, 1249 (1970). Dronabinol remains in Schedule I today, with one notable exception. The United States Food and Drug Administration (FDA), after extensive testing and research, approved the drug Marinol -- described as dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule -- for treatment of nausea associated with cancer patients and anorexia associated with weight loss in AIDS patients. 51 Fed. Reg. 17,476, 17,478 (1986). As a result of this FDA approval, the United States Drug Enforcement Administration (DEA) eventually assigned dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in an FDA approved product to Schedule III. 21 C.F.R. § 1308.13(g)(1); 64 Fed. Reg. 35,928 (1999). The DEA was careful to stress, however, that it was rescheduling dronabinol only in an FDA approved drug product. 51 Fed. Reg. 17,477. All other "mixtures, compounds, and preparations" containing dronabinol remained in Schedule I. 51 Fed. Reg. 17,477. In practical effect, only the brand name drug Marinol was moved to Schedule III. Go To Headnote

Lee v. Clark County Juvenile Court, 2005 U.S. Dist. LEXIS 35457 (WD Wash Dec. 2, 2005).

Overview: *Employee could not establish she was "qualified individual with a disability" under ADA. Employee, a care coordinator/omental health therapist, ordered refill for a patient's Vicodin prescription and picked it up under a false name; thus, the employee engaged in criminal conduct, and the employer was entitled to terminate her without violating ADA..*

- Vicodin is a schedule III controlled substance. 21 U.S.C.S. § 812; 21 C.F.R. § 1308.13. Go To Headnote

Criminal Law & Procedure : Criminal Offenses : Miscellaneous Offenses : Goods Smuggling : General Overview

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Research References & Practice Aids

NOTES APPLICABLE TO ENTIRE TITLE:

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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