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The HHSC local offices will post this notice for 30 days.

TRD-202004223

Karen Ray

Chief Counsel

Texas Health and Human Services Commission

Filed: October 12, 2020

Department of State Health Services

Order Removing Approved Cannabidiol Drugs from Schedule V, the Addition of Cenobamate to Schedule V and the addition of Isotonitazene to Schedule I Temporarily Scheduled Substances

The Drug Enforcement Administration (DEA) issued an interim final rule to codify statutory amendments to the Controlled Substances Act (CSA) made by the Agriculture Improvement Act of 2018 (AIA), regarding the scope of regulatory controls over marijuana-related constituents. This interim final rule was published in the *Federal Register*, Volume 85, Number 163, Pages 51639-51645, and takes effect August 21, 2020.

The order removes from schedule V 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-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols."

The Drug Enforcement Administration issued a final rule adopting, without change, an interim final rule with request for comments published in the *Federal Register* on March 10, 2020, placing cenobamate [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate, including its salts, in schedule V of the Controlled Substances Act. This final rule was published in the *Federal Register*, Volume 85, Number 162, pages 51340-51342, and takes effect August 20, 2020.

The Acting Administrator of the Drug Enforcement Administration issued a temporary order to schedule *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine (commonly known as isotonitazene), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, in schedule I. This

temporary scheduling action was published in the *Federal Register*, Volume 85, Number 162, pages 51342-51346, and takes effect August 20, 2020. The action was taken for the following reasons:

1. Isotonitazene has high potential for abuse;
2. There is currently no accepted medical use in treatment in the United States;
3. There is a lack of accepted safety for use under medical supervision; and
4. Control of isotonitazene is necessary to avoid an imminent hazard to public safety.

Pursuant to Section 481.034(g), as amended by the 75th legislature, of the Texas Controlled Substances Act, Health and Safety Code, Chapter 481, at least thirty-one days have expired since notice of the above referenced actions was published in the *Federal Register*. In the capacity as Commissioner of the Texas Department of State Health Services, John Hellerstedt, M.D., does hereby order the removal of approved cannabidiol drugs from Schedule V; adoption of a final rule placing cenobamate in schedule V; and the placement of isotonitazene into schedule I temporarily controlled substances.

-Schedule I temporarily listed substances subject to emergency scheduling by the U.S. Drug Enforcement Administration.

Unless specifically excepted or unless listed in another schedule, a material, compound, mixture, or preparation that contains any quantity of the following substances or that contains any of the substance's salts, isomers, and salts of isomers if the existence of the salts, isomers, and salts of isomers is possible within the specific chemical designation:

- (1) *N*-(1-Phenethylpiperidin-4-yl)-*N*-phenylpentanamide (Other name: valeryl fentanyl);
- (2) *N*-(4-Methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)butyramide (Other name: *p*-methoxybutyryl fentanyl);
- (3) *N*-(4-Chlorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide (Other name: *p*-chloroisobutyryl fentanyl);
- (4) *N*-(1-Phenethylpiperidin-4-yl)-*N*-phenylisobutyramide (Other name: isobutyryl fentanyl);
- (5) *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylcyclopentanecarboxamide (Other name: cyclopentyl fentanyl);
- (6) Fentanyl-related substances.
 - (6-1) Fentanyl-related substance means any substance not otherwise listed under another Administration Controlled Substance Code Number, and for which no exemption or approval is in effect under Section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355], that is structurally related to fentanyl by one or more of the following modifications:
 - (6-1-1) Replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle;
 - (6-1-2) Substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino or nitro groups;
 - (6-1-3) Substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino or nitro groups;
 - (6-1-4) Replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle; and/or
 - (6-1-5) Replacement of the *N*-propionyl group by another acyl group;

(6-2) This definition includes, but is not limited to, the following substances:

(6-2-1) *N*-(1-(2-Fluorophenethyl)piperidin-4-yl)-*N*-(2-fluorophenyl)propionamide (Other name: 2'-fluoro-*o*-fluorofentanyl);

(6-2-2) *N*-(2-Methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)acetamide (Other name: *o*-methyl acetylfentanyl);

(6-2-3) *N*-(1-Phenethylpiperidin-4-yl)-*N*,3-diphenylpropanamide (Other names: β'-phenyl fentanyl; hydrocinnamoyl fentanyl);

(6-2-4) *N*-(1-Phenethylpiperidin-4-yl)-*N*-phenylthiophene-2-carboxamide (Other name: thiofuranyl fentanyl);

(6-2-5) (E)-*N*-(1-Phenethylpiperidin-4-yl)-*N*-phenylbut-2-enamide (Other name: crotonyl fentanyl);

(7) Naphthalen-1-yl-1-(5-fluoropentyl)-1*H*-indole-3-carboxylate (Other names: NM2201; CBL2201);

(8) *N*-(1-Amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indazole-3-carboxamide (Other name: 5F-AB-PINACA);

(9) 1-(4-Cyanobutyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (Other names: 4-CN-CUMYL-BUTINACA; 4-cyano-CUMYL-BUTINACA; 4-CN-CUMYL-BINACA; CUMYL-4CN-BINACA; SGT-78);

(10) Methyl 2-(1-(cyclohexylmethyl)-1*H*-indole-3-carboxamido)-3-methylbutanoate (Other names: MMB-CHMICA; AMB-CHMICA);

(11) 1-(5-Fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-pyrrolo[2,3-*b*]pyridine-3-carboxamide (Other name: 5F-CUMYL-P7AICA);

(12) *N*-ethylpentylone (Other names: ephylone, 1-(1,3-benzodioxil-5-yl)-2-(ethylamino)-pentan-1-one);

(13) Ethyl 2-(1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate (Other name: 5F-EDMB-PINACA);

(14) Methyl 2-(1-(5-fluoropentyl)-1*H*-indole-3-carboxamido)-3,3-dimethylbutanoate (Other name: 5F-MDMB-PICA);

(15) *N*-(Adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide (Other names: FUB-AKB48; FUB-APINACA; AKB48 *N*-(4-FLUOROBENZYL));

(16) 1-(5-Fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide (Other names: 5F-CUMYL-PINACA; SGT-25);

(17) (1-(4-Fluorobenzyl)-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)methanone (Other name: FUB-144);

(18) *N*-Ethylhexedrone (Other name: 2-(ethylamino)-1-phenylhexan-1-one);

(19) α-pyrrolidinohexanophenone (Other names: α-PHP; α-pyrrolidinohexiophenone; 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one);

(20) 4-Methyl-α-ethylaminopentiophenone (Other names: 4-MEAP; 2-(ethylamino)-1-(4-methylphenyl)pentan-1-one);

(21) 4-Methyl-α-pyrrolidinohexiophenone (Other names: MPHP, 4'-methyl- α-pyrrolidinohexanophenone; 1-(4-methylphenyl)-2-(pyrrolidin-1-yl)hexan-1-one);

(22) α-pyrrolidinoheptaphenone (Other names: PV8; 1-phenyl-2-(pyrrolidin-1-yl)heptan-1-one); and

(23) 4-Chloro-α-pyrrolidinovalerophenone (Other names: 4-chloro-α-PVP; 4-chloro-α-pyrrolidinopentiophenone; 1-(4-chlorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one); and

*(24) *N,N*-diethyl-2-(2-(4 isopropoxybenzyl)-5-nitro-1*H*-benzimidazol-1-yl)ethan-1-amine, its isomers, esters, ethers, salts and

salts of isomers, esters and ethers (Other names: isotonitazene; *N,N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine)

-Schedule V 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 ((2*S*)-2-[(4*R*)-2-oxo-4-propylpyrrolidin-1-yl]butanamide) (Other names; BRV; UCB-34714; and Briviact);

*(2) Cenobamate [(1*R*)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate;

(3) Ezogabine including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers and salts of isomers is possible;

(4) Lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide];

(5) Lasmiditan [2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)benzamide]; and

(6) Pregabalin [(*S*)-3-(aminomethyl)-5-methylhexanoic acid].

NUMBER 7 IS REMOVED FROM SCHEDULE V DEPRESSANTS

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

TRD-202004270

Barbara L. Klein

General Counsel

Department of State Health Services

Filed: October 14, 2020

Texas Higher Education Coordinating Board

Meeting of Negotiated Rulemaking Committee on Minority Health Research & Education Grant Program

Date of Meeting: October 28, 2020

Start Time of Meeting: 09:30 a.m.

Street Location: This meeting will be held via audio conference. A link to the audio conference will be available at <https://www.highered.texas.gov/>.

Additional Information Obtained From: Laurie Frederick, Convener, (512) 427-6446, Laurie.Frederick@highered.texas.gov.

Agenda:

1. Introductions
2. Brief Overview of the Negotiated Rulemaking Process: What it is, What it's not
3. Brief Overview of Roles and Responsibilities
 - a) Role of Facilitator
 - b) Role of Sponsor Agency
 - c) Role of Committee Members