

3768, which enacted sections 801a, 830, and 852 of this title, amended sections 352, 802, 811, 812, 823, 827, 841 to 843, 872, 881, 952, 953, and 965 of this title and section 242a of Title 42, The Public Health and Welfare, repealed section 830 of this title effective Jan. 1, 1981, and enacted provisions set out as notes under sections 801, 801a, 812, and 830 of this title. For complete classification of this Act to the Code, see Short Title of 1978 Amendment note set out under section 801 of this title and Tables.

This subchapter and subchapter II of this chapter, referred to in subsec. (g)(1), was in the original "titles II and III of the Comprehensive Drug Abuse Prevention and Control Act", which was translated as meaning titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, 1285, as amended, to reflect the probable intent of Congress. Title II is classified principally to this subchapter and part A of title III comprises subchapter II of this chapter. For complete classification of this Act to the Code, see Short Title notes set out under section 801 of this title and Tables.

AMENDMENTS

2004—Subsec. (g)(1). Pub. L. 108-358, §2(b)(1), substituted "drug which contains a controlled substance from the application of this subchapter and subchapter II of this chapter if such drug" for "substance from a schedule if such substance".

Subsec. (g)(3)(C). Pub. L. 108-358, §2(b)(2), added subpar. (C).

1984—Subsec. (g)(3). Pub. L. 98-473, §509(a), added par. (3).

Subsec. (h). Pub. L. 98-473, §508, added subsec. (h).

1978—Subsec. (d). Pub. L. 95-633 designated existing provisions as par. (1) and added pars. (2) to (5).

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (d)(2), (3), (4)(A), (B), (5) pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 2004 AMENDMENT

Amendment by Pub. L. 108-358 effective 90 days after Oct. 22, 2004, see section 2(d) of Pub. L. 108-358, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

§ 812. Schedules of controlled substances

(a) Establishment

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect

to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has no currently accepted medical use in treatment in the United States.

(C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.—

(A) The drug or other substance has a high potential for abuse.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.

(C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.—

(A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.—

(A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.

(B) The drug or other substance has a currently accepted medical use in treatment in the United States.

(C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended¹ pursuant to section 811 of this title, consist of the following drugs or other substances, by whatever official name, common or usual name, chemical name, or brand name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers,

¹ Revised schedules are published in the Code of Federal Regulations, Part 1308 of Title 21, Food and Drugs.

salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol.
- (2) Allylprodine.
- (3) Alphacetylmethadol.²
- (4) Alphameprodine.
- (5) Alphamethadol.
- (6) Benzethidine.
- (7) Betacetylmethadol.
- (8) Betameprodine.
- (9) Betamethadol.
- (10) Betaprodine.
- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Dextrorphan.
- (14) Diampromide.
- (15) Diethylthiambutene.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxeridine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacetylmorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.
- (39) Propheptazine.
- (40) Properidine.
- (41) Racemoramide.
- (42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, their 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) Acetorphine.
- (2) Acetyldihydrocodeine.
- (3) Benzylmorphine.
- (4) Codeine methylbromide.
- (5) Codeine-N-Oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Etorphine.
- (10) Heroin.
- (11) Hydromorphanol.
- (12) Methyl-desorphine.
- (13) Methylhydromorphine.
- (14) Morphine methylbromide.
- (15) Morphine methylsulfonate.
- (16) Morphine-N-Oxide.

- (17) Myrophine.
- (18) Nicocodeine.
- (19) Nicomorphine.
- (20) Normorphine.
- (21) Pholcodine.
- (22) Thebacon.

(c) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their 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) 3,4-methylenedioxy amphetamine.
- (2) 5-methoxy-3,4-methylenedioxy amphetamine.
- (3) 3,4,5-trimethoxy amphetamine.
- (4) Bufotenine.
- (5) Diethyltryptamine.
- (6) Dimethyltryptamine.
- (7) 4-methyl-2,5-diamethoxyamphetamine.
- (8) Ibogaine.
- (9) Lysergic acid diethylamide.
- (10) Marihuana.
- (11) Mescaline.
- (12) Peyote.
- (13) N-ethyl-3-piperidyl benzilate.
- (14) N-methyl-3-piperidyl benzilate.
- (15) Psilocybin.
- (16) Psilocyn.
- (17) Tetrahydrocannabinols.

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca³ leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

² So in original. Probably should be "Alphacetylmethadol."

³ So in original. Probably should be capitalized.

- (1) Alphaprodine.
- (2) Anileridine.
- (3) Bezitramide.
- (4) Dihydrocodeine.
- (5) Diphenoxylate.
- (6) Fentanyl.
- (7) Isomethadone.
- (8) Levomethorphan.
- (9) Levorphanol.
- (10) Metazocine.
- (11) Methadone.
- (12) Methadone-Intermediate, 4-cyano-2-dimethylamino-4,4-diphenyl butane.
- (13) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.
- (14) Pethidine.
- (15) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.
- (16) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.
- (17) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.
- (18) Phenazocine.
- (19) Piminodine.
- (20) Racemethorphan.
- (21) Racemorphan.

(c) Unless specifically excepted or unless listed in another schedule, any injectable liquid which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.

SCHEDULE III

(a) 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:

- (1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.
- (2) Phenmetrazine and its salts.
- (3) Any substance (except an injectable liquid) which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers.
- (4) Methylphenidate.

(b) 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 substance which contains any quantity of a derivative of barbituric acid, or any salt of a derivative of barbituric acid.
- (2) Chorexadol.
- (3) Glutethimide.
- (4) Lysergic acid.
- (5) Lysergic acid amide.
- (6) Methyprylon.
- (7) Phencyclidine.
- (8) Sulfondiethylmethane.
- (9) Sulfonethylmethane.
- (10) Sulfonmethane.

(c) Nalorphine.

(d) Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, or any salts thereof:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) 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, non-narcotic ingredients in recognized therapeutic amounts.

(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(5) 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.

(6) 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.

(7) 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.

(8) 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.

(e) Anabolic steroids.

SCHEDULE IV

- (1) Barbital.
- (2) Chloral betaine.
- (3) Chloral hydrate.
- (4) Ethchlorvynol.
- (5) Ethinamate.
- (6) Methohexital.
- (7) Meprobamate.
- (8) Methylphenobarbital.
- (9) Paraldehyde.
- (10) Petrichloral.
- (11) Phenobarbital.

SCHEDULE V

Any compound, mixture, or preparation containing any of the following limited quantities of narcotic drugs, which shall include one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the narcotic drug 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.

(Pub. L. 91-513, title II, §202, Oct. 27, 1970, 84 Stat. 1247; Pub. L. 95-633, title I, §103, Nov. 10, 1978, 92 Stat. 3772; Pub. L. 98-473, title II, §§507(c), 509(b), Oct. 12, 1984, 98 Stat. 2071, 2072; Pub. L. 99-570, title I, §1867, Oct. 27, 1986, 100 Stat. 3207-55; Pub. L. 99-646, §84, Nov. 10, 1986, 100 Stat. 3619; Pub. L. 101-647, title XIX, §1902(a), Nov. 29, 1990, 104 Stat. 4851.)

AMENDMENTS

1990—Subsec. (c). Pub. L. 101-647 added item (e) at end of schedule III.

1986—Subsec. (c). Pub. L. 99-646 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves (except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed); cocaine, its salts, optical and geometric isomers, and salts of isomers; and ecgonine, its derivatives, their salts, isomers, and salts of isomers."

Pub. L. 99-570 amended schedule II(a)(4) generally. Prior to amendment, schedule II(a)(4) read as follows: "Coca leaves and any salt, compound, derivative, or preparation of coca leaves (including cocaine and ecgonine and their salts, isomers, derivatives, and salts of isomers and derivatives), and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, except that the substances shall not include decocainized coca leaves or extraction of coca leaves, which extractions do not contain cocaine or ecgonine."

1984—Subsec. (c). Pub. L. 98-473, §507(c), in schedule II(a)(4) added applicability to cocaine and ecgonine and their salts, isomers, etc.

Subsec. (d). Pub. L. 98-473, §509(b), struck out subsec. (d) which related to authority of Attorney General to exempt stimulants or depressants containing active medicinal ingredients.

1978—Subsec. (d)(3). Pub. L. 95-633 added cl. (3).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-647 effective 90 days after Nov. 29, 1990, see section 1902(d) of Pub. L. 101-647, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 1978 AMENDMENT

Amendment by Pub. L. 95-633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

CONGRESSIONAL FINDING; EMERGENCY SCHEDULING OF GHB IN CONTROLLED SUBSTANCES ACT

Pub. L. 106-172, §§2, 3(a), Feb. 18, 2000, 114 Stat. 7, 8, provided that:

"SEC. 2. FINDINGS.

"Congress finds as follows:

"(1) Gamma hydroxybutyric acid (also called G, Liquid X, Liquid Ecstasy, Grievous Bodily Harm, Georgia Home Boy, Scoop) has become a significant and growing problem in law enforcement. At least 20 States have scheduled such drug in their drug laws and law enforcement officials have been experiencing an increased presence of the drug in driving under the influence, sexual assault, and overdose cases especially at night clubs and parties.

"(2) A behavioral depressant and a hypnotic, gamma hydroxybutyric acid ('GHB') is being used in conjunction with alcohol and other drugs with detrimental effects in an increasing number of cases. It is difficult to isolate the impact of such drug's ingestion since it is so typically taken with an ever-changing array of other drugs and especially alcohol which potentiates its impact.

"(3) GHB takes the same path as alcohol, processes via alcohol dehydrogenase, and its symptoms at high levels of intake and as impact builds are comparable to alcohol ingestion/intoxication. Thus, aggression and violence can be expected in some individuals who use such drug.

"(4) If taken for human consumption, common industrial chemicals such as gamma butyrolactone and 1,4-butanediol are swiftly converted by the body into GHB. Illicit use of these and other GHB analogues and precursor chemicals is a significant and growing law enforcement problem.

"(5) A human pharmaceutical formulation of gamma hydroxybutyric acid is being developed as a treatment for cataplexy, a serious and debilitating disease. Cataplexy, which causes sudden and total loss of muscle control, affects about 65 percent of the estimated 180,000 Americans with narcolepsy, a sleep disorder. People with cataplexy often are unable to work, drive a car, hold their children or live a normal life.

"(6) Abuse of illicit GHB is an imminent hazard to public safety that requires immediate regulatory action under the Controlled Substances Act (21 U.S.C. 801 et seq.).

"SEC. 3. EMERGENCY SCHEDULING OF GAMMA HYDROXYBUTYRIC ACID AND LISTING OF GAMMA BUTYROLACTONE AS LIST I CHEMICAL.

"(a) EMERGENCY SCHEDULING OF GHB.—

"(1) IN GENERAL.—The Congress finds that the abuse of illicit gamma hydroxybutyric acid is an imminent hazard to the public safety. Accordingly, the Attorney General, notwithstanding sections 201(a), 201(b), 201(c), and 202 of the Controlled Substances Act [21 U.S.C. 811(a)-(c), 812], shall issue, not later than 60 days after the date of the enactment of this Act [Feb. 18, 2000], a final order that schedules such drug (together with its salts, isomers, and salts of isomers) in the same schedule under section 202(c) of the Controlled Substances Act as would apply to a scheduling of a substance by the Attorney General under section 201(h)(1) of such Act (relating to imminent hazards to the public safety), except as follows:

"(A) For purposes of any requirements that relate to the physical security of registered manufacturers and registered distributors, the final order shall treat such drug, when the drug is manufactured, distributed, or possessed in accordance with an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] (whether the exemption involved is authorized before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), as being in the same schedule as that recommended by the Secretary of Health and Human Services for the drug when the drug is the subject of an authorized investigational new drug application (relating to such section 505(i)). The recommendation referred to in the preceding sentence is contained in the first paragraph of the letter transmitted on May 19, 1999, by such Secretary (acting through the Assistant Secretary for Health) to the Attorney General (acting through the Deputy Administrator of the Drug Enforcement Administration), which letter was in response to the letter transmitted by the Attorney General (acting through such Deputy Administrator) on September 16, 1997. In publishing the final order in the Federal Register, the Attorney General shall publish a copy of the letter that was transmitted by the Secretary of Health and Human Services.

"(B) In the case of gamma hydroxybutyric acid that is contained in a drug product for which an application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355] (whether the application involved is approved before, on, or after the date of the enactment of this Act [Feb. 18, 2000]), the final order shall schedule such drug in the same schedule as that recommended by the Secretary of Health and Human

Services for authorized formulations of the drug. The recommendation referred to in the preceding sentence is contained in the last sentence of the fourth paragraph of the letter referred to in subparagraph (A) with respect to May 19, 1999.

“(2) FAILURE TO ISSUE ORDER.—If the final order is not issued within the period specified in paragraph (1), gamma hydroxybutyric acid (together with its salts, isomers, and salts of isomers) is deemed to be scheduled under section 202(c) of the Controlled Substances Act [21 U.S.C. 812(c)] in accordance with the policies described in paragraph (1), as if the Attorney General had issued a final order in accordance with such paragraph.”

PLACEMENT OF PIPRADROL AND SPA IN SCHEDULE IV TO CARRY OUT OBLIGATION UNDER CONVENTION ON PSYCHOTROPIC SUBSTANCES

Section 102(c) of Pub. L. 95-633 provided that: “For the purpose of carrying out the minimum United States obligations under paragraph 7 of article 2 of the Convention on Psychotropic Substances, signed at Vienna, Austria, on February 21, 1971, with respect to pipradrol and SPA (also known as (-)-1-dimethylamino-1,2-diphenylethane), the Attorney General shall by order, made without regard to sections 201 and 202 of the Controlled Substances Act [this section and section 811 of this title], place such drugs in schedule IV of such Act [see subsec. (c) of this section].”

Provision of section 102(c) of Pub. L. 95-633, set out above, effective on the date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95-633, set out as an Effective Date note under section 801a of this title.

§ 813. Treatment of controlled substance analogues

A controlled substance analogue shall, to the extent intended for human consumption, be treated, for the purposes of any Federal law as a controlled substance in schedule I.

(Pub. L. 91-513, title II, §203, as added Pub. L. 99-570, title I, §1202, Oct. 27, 1986, 100 Stat. 3207-13; amended Pub. L. 100-690, title VI, §6470(c), Nov. 18, 1988, 102 Stat. 4378.)

REFERENCES IN TEXT

Schedule I, referred to in text, is set out in section 812(c) of this title.

AMENDMENTS

1988—Pub. L. 100-690 substituted “any Federal law” for “this subchapter and subchapter II of this chapter”.

§ 814. Removal of exemption of certain drugs

(a) Removal of exemption

The Attorney General shall by regulation remove from exemption under section 802(39)(A)(iv) of this title a drug or group of drugs that the Attorney General finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance.

(b) Factors to be considered

In removing a drug or group of drugs from exemption under subsection (a) of this section, the Attorney General shall consider, with respect to a drug or group of drugs that is proposed to be removed from exemption—

- (1) the scope, duration, and significance of the diversion;
- (2) whether the drug or group of drugs is formulated in such a way that it cannot be easily

used in the illicit production of a controlled substance; and

- (3) whether the listed chemical can be readily recovered from the drug or group of drugs.

(c) Specificity of designation

The Attorney General shall limit the designation of a drug or a group of drugs removed from exemption under subsection (a) of this section to the most particularly identifiable type of drug or group of drugs for which evidence of diversion exists unless there is evidence, based on the pattern of diversion and other relevant factors, that the diversion will not be limited to that particular drug or group of drugs.

(d) Reinstatement of exemption with respect to particular drug products

(1) Reinstatement

On application by a manufacturer of a particular drug product that has been removed from exemption under subsection (a) of this section, the Attorney General shall by regulation reinstate the exemption with respect to that particular drug product if the Attorney General determines that the particular drug product is manufactured and distributed in a manner that prevents diversion.

(2) Factors to be considered

In deciding whether to reinstate the exemption with respect to a particular drug product under paragraph (1), the Attorney General shall consider—

- (A) the package sizes and manner of packaging of the drug product;
- (B) the manner of distribution and advertising of the drug product;
- (C) evidence of diversion of the drug product;
- (D) any actions taken by the manufacturer to prevent diversion of the drug product; and
- (E) such other factors as are relevant to and consistent with the public health and safety, including the factors described in subsection (b) of this section as applied to the drug product.

(3) Status pending application for reinstatement

A transaction involving a particular drug product that is the subject of a bona fide pending application for reinstatement of exemption filed with the Attorney General not later than 60 days after a regulation removing the exemption is issued pursuant to subsection (a) of this section shall not be considered to be a regulated transaction if the transaction occurs during the pendency of the application and, if the Attorney General denies the application, during the period of 60 days following the date on which the Attorney General denies the application, unless—

- (A) the Attorney General has evidence that, applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; and
- (B) the Attorney General so notifies the applicant.

(4) Amendment and modification

A regulation reinstating an exemption under paragraph (1) may be modified or revoked with