

- (7) French Guiana
- (8) Guyana
- (9) Panama
- (10) Paraguay
- (11) Peru
- (12) Suriname
- (13) Uruguay
- (14) Venezuela

(c) Domestic transactions of Methyl Isobutyl Ketone (MIBK).

(d) Import transactions of Methyl Isobutyl Ketone (MIBK) destined for the United States.

(e) Export transactions, international transactions, and import transactions for transshipment or transfer of Methyl Isobutyl Ketone (MIBK) destined for Canada or any country outside of the Western Hemisphere.

(f) Domestic and international transactions of Lugol's Solution (consisting of 5 percent iodine and 10 percent potassium iodide in an aqueous solution) in original manufacturer's packaging of one-fluid-ounce (30 milliliters) or less, and no greater than one package per transaction.

(g) Import transactions of anhydrous hydrogen chloride.

(h) Domestic distribution of anhydrous hydrogen chloride weighing 12,000 pounds (net weight) or more in a single container.

(i) Domestic distribution of anhydrous hydrogen chloride by pipeline.

(j) Domestic and international return shipments of reusable containers from customer to producer containing residual quantities of red phosphorus or white phosphorus in rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(k) Domestic, import, and export distributions of gamma-butyrolactone weighing 4,000 kilograms (net weight) or more in a single container.

(l) Domestic and import transactions in chemical mixtures that contain acetone, ethyl ether, 2-butanone, and/or toluene, unless regulated because of being formulated with other List I or

List II chemical(s) above the concentration limit.

[57 FR 43615, Sept. 22, 1992, as amended at 60 FR 19510, Apr. 19, 1995; 60 FR 32461, June 22, 1995; 62 FR 13968, Mar. 24, 1997; 65 FR 47316, Aug. 2, 2000; 66 FR 52675, Oct. 17, 2001; 68 FR 37414, June 24, 2003; 68 FR 53292, Sept. 10, 2003; 69 FR 74971, Dec. 15, 2004; 72 FR 10928, Mar. 12, 2007; 72 FR 35931, July 2, 2007]

§ 1310.09 Temporary exemption from registration.

(a) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before July 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to paragraph (1)(iv) of the definition of regulated transaction in § 1300.02 of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(c) Each person required by section 302 of the act (21 U.S.C. 822) to obtain a registration to distribute, import, or export GBL is temporarily exempted from the registration requirement, provided that the DEA receives a proper application for registration on or before July 24, 2000. The exemption will remain in effect for each person who

§ 1310.09

21 CFR Ch. II (4–1–23 Edition)

has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(d) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export the List I chemicals red phosphorus, white phosphorus, and hypophosphorous acid (and its salts), is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 17, 2001. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(e) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures which contain ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine, pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before June 30, 2003. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date

of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(f) Except for chemical mixtures containing the listed chemicals in paragraph (e) of this section, each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export regulated chemical mixtures, pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption on or before February 14, 2005. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(g) Any person who distributes, imports, or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(h) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated N-phenethyl-4-piperidone (NPP), including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing NPP pursuant to §1310.13 on or before June 22, 2007. The exemption will remain in effect for

each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports or exports a chemical mixture containing N-phenethyl-4-piperidone (NPP) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(i) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to manufacture, distribute, import, or export regulated iodine, including regulated iodine chemical mixtures pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that the Administration receives a proper application for registration or application for exemption for a chemical mixture containing iodine on or before August 31, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, and 1313 of this chapter remain in full force and effect. Any person who distributes, imports, or exports a chemical mixture containing iodine whose application for exemption is subsequently denied by the Administration must obtain a registration with the Administration. A temporary exemption from the registration requirement will also be provided for these persons, provided that the Administration receives a properly completed applica-

tion for registration on or before 30 days following the date of official Administration notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until the Administration takes final action on their registration application.

(j) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain ephedrine, and/or pseudoephedrine, pursuant to Sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before August 24, 2007. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, 1313, and 1315 of this chapter remain in full force and effect. Any person who manufactures, distributes, imports, or exports a chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for these persons, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(k)(1) Each person required by sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated GBL-containing chemical mixtures, pursuant to sections 1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption

§ 1310.09

on or before July 29, 2010. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a GBL-containing chemical mixture whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(1)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated ergocristine and its salts, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing ergocristine and its salts pursuant to §1310.13 on or before May 2, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing ergocristine and its salts whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will

21 CFR Ch. II (4–1–23 Edition)

also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(m)(1) Each person required by Sections 302 or 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated chemical mixtures which contain red phosphorus, white phosphorus, hypophosphorous acid (and its salts), pursuant to §§1310.12 and 1310.13, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption on or before July 5, 2011. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture which contains red phosphorus, white phosphorus, hypophosphorous acid (and its salts) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has not been approved. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(n)(1) Each person required under sections 302 and 1007 of the Act (21 U.S.C. 822, 957) to obtain a registration to manufacture, distribute, import, or export regulated alpha-phenylacetoacetonitrile (APAAN) and

its salts, optical isomers, and salts of optical isomers, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that the DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing alpha-phenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, pursuant to §1310.13 on or before August 14, 2017. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing alpha-phenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers whose application for exemption is subsequently denied by the DEA must obtain a registration with the DEA. A temporary exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that the DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until the DEA takes final action on their registration application.

(o)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing benzylfentanyl pursuant to §1310.13 on or before May 15, 2020. The exemption will remain in effect for each person

who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing *N*-(1-benzylpiperidin-4-yl)-*N*-phenylpropionamide (benzylfentanyl) and its salts whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(p)(1) Each person required under 21 U.S.C. 822 and 21 U.S.C. 957 to obtain a registration to manufacture, distribute, import, or export regulated *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-piperidinamine, 4-AP) and its amides, its carbamates, and its salts, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a proper application for registration or application for exemption for a chemical mixture containing 4-anilinopiperidine pursuant to §1310.13 on or before May 15, 2020. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing *N*-phenylpiperidin-4-amine (4-anilinopiperidine; *N*-phenyl-4-

§ 1310.09

piperidinamine; 4-AP) and its amides, its carbamates, and its salts whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement will also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(q)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), and *alpha*-phenylacetoacetamide (APAA), including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) pursuant to §1310.13 on or before (30 days after publication of a rule implementing regulations regarding these three chemicals). The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports or exports a chemical mixture containing regulated forms of 3,4-MDP-2-P methyl glycidate (PMK glycidate), 3,4-MDP-2-P methyl glycidic acid (PMK glycidic acid), or *alpha*-phenylacetoacetamide (APAA) whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary

21 CFR Ch. II (4–1–23 Edition)

exemption from the registration requirement will also be provided for those persons whose applications for exemption are denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons will remain in effect until DEA takes final action on their registration application.

(r)(1) Each person required under 21 U.S.C. 822 and 957 to obtain a registration to manufacture, distribute, import, or export regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers, including regulated chemical mixtures pursuant to §1310.12, is temporarily exempted from the registration requirement, provided that DEA receives a properly completed application for registration or application for exemption for a chemical mixture containing regulated forms of MAPA pursuant to §1310.13 on or before December 20, 2021. The exemption would remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in the Act and parts 1309, 1310, 1313, and 1316 of this chapter remain in full force and effect.

(2) Any person who manufactures, distributes, imports, or exports a chemical mixture containing regulated forms of methyl *alpha*-phenylacetoacetate (MAPA; methyl 3-oxo-2-phenylbutanoate) and its optical isomers whose application for exemption is subsequently denied by DEA must obtain a registration with DEA. A temporary exemption from the registration requirement would also be provided for those persons whose application for exemption is denied, provided that DEA receives a properly completed application for registration on or before 30 days following the date of official DEA notification that the application for exemption has been denied. The temporary exemption for such persons would remain in effect

until DEA takes final action on their registration application.

[62 FR 27693, May 21, 1997, as amended at 62 FR 53960, Oct. 17, 1997; 65 FR 21647, Apr. 24, 2000; 66 FR 52675, Oct. 17, 2001; 68 FR 23203, May 1, 2003; 69 FR 74971, Dec. 15, 2004; 72 FR 20046, Apr. 23, 2007; 72 FR 35931, July 2, 2007; 72 FR 40239, July 24, 2007; 72 FR 40744, July 25, 2007; 75 FR 37306, June 29, 2010; 76 FR 17781, Mar. 31, 2011; 76 FR 31829, June 2, 2011; 77 FR 4237, Jan. 27, 2012; 82 FR 32460, July 14, 2017; 85 FR 20828, Apr. 15, 2020; 86 FR 24707, May 7, 2021; 86 FR 64366, Nov. 18, 2021]

§ 1310.10 Removal of the exemption of drugs distributed under the Federal Food, Drug and Cosmetic Act.

(a) The Administrator may remove from exemption under paragraph (1)(iv) of the definition of regulated transaction in §1300.02 of this chapter any drug or group of drugs that the Administrator finds is being diverted to obtain a listed chemical for use in the illicit production of a controlled substance. In removing a drug or group of drugs from the exemption the Administrator shall consider:

- (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.

(b) Upon determining that a drug or group of drugs should be removed from the exemption under paragraph (a) of this section, the Administrator shall issue and publish in the FEDERAL REGISTER his proposal to remove the drug or group of drugs from the exemption, which shall include a reference to the legal authority under which the proposal is based. The Administrator shall permit any interested person to file written comments on or objections to the proposal. After considering any comments or objections filed, the Administrator shall publish in the FEDERAL REGISTER his final order.

(c) The Administrator shall limit the removal of a drug or group of drugs from exemption under paragraph (a) of this section to the most identifiable type of the drug or group of drugs for which evidence of diversion exists un-

less 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) Any manufacturer seeking reinstatement of a particular drug product that has been removed from an exemption may apply to the Administrator for reinstatement of the exemption for that particular drug product on the grounds that the particular drug product is manufactured and distributed in a manner that prevents diversion. In determining whether the exemption should be reinstated the Administrator shall consider:

- (1) The package sizes and manner of packaging of the drug product;
- (2) The manner of distribution and advertising of the drug product;
- (3) Evidence of diversion of the drug product;
- (4) Any actions taken by the manufacturer to prevent diversion of the drug product; and
- (5) Such other factors as are relevant to and consistent with the public health and safety, including the factors described in paragraph (a) of this section as applied to the drug product.

(e) Within a reasonable period of time after receipt of the application for reinstatement of the exemption, the Administrator shall notify the applicant of his acceptance or non-acceptance of his application, and if not accepted, the reason therefor. If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER his order on the reinstatement of the exemption for the particular drug product, which shall include a reference to the legal authority under 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. If any such comments 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.