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PART 1310 —RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES; IMPORTATION AND EXPORTATION OF CERTAIN MACHINES

§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 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, Nmethylephedrine, 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.

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(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 Nphenethyl-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 application 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 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

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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.

(I)(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 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 alphaphenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, including regulated chemical mixtures pursuant to **Sec. 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 alphaphenylacetoacetonitrile (APAAN) and its salts, optical isomers, and salts of optical isomers, pursuant to **Sec. 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

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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.

[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]