

PART 1309 — REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

REQUIREMENTS FOR REGISTRATION

§1309.25 Temporary exemption from registration for chemical registration applicants

(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 this part **1309** and parts **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 pseudoephedrine or phenylpropanolamine drug product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before October 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 this part **1309** and parts **1310** and **1313** of this chapter remain in full force and effect.

(c) Each person required by sections 302 or 1007 of the Act **21 U.S.C. 822** or **957**) to obtain a registration to manufacture or import prescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before March 3, 2010. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied the application. This exemption applies only to registration; all other chemical control requirements set forth in this part and parts **1310**, **1313**, and **1315** of this chapter remain in full force and effect.

[67 FR 14860, Mar. 28, 2002, as amended at 75 FR 4982, Feb. 1, 2010]