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 respect to a particular drug product upon a finding that—

(A) applying the factors described in subsection (b) of this section to the drug product, the drug product is being diverted; or

(B) there is a significant change in the data that led to the issuance of the regulation.

(Pub. L. 91–513, title II, § 204, as added Pub. L. 103–200, § 2(b)(1), Dec. 17, 1993, 107 Stat. 2334; amended Pub. L. 104–237, title IV, § 401(c), Oct. 3, 1996, 110 Stat. 3108; Pub. L. 109–177, title VII, § 712(a)(2), Mar. 9, 2006, 120 Stat. 263.)

AMENDMENTS

2006—Subsec. (e). Pub. L. 109–177 struck out subsec. (e). Text read as follows: ''Pursuant to subsection (d)(1) of this section, the Attorney General shall by regulation reinstate the exemption with respect to a particular ephedrine, pseudoephedrine, or phenylpropanolamine drug product if the Attorney General determines that the drug product is manufactured and distributed in a manner that prevents diversion. In making this determination the Attorney General shall consider the factors listed in subsection (d)(2) of this section. Any regulation issued pursuant to this subsection may be amended or revoked based on the factors listed in subsection (d)(4) of this section.''

1996—Subsec. (e). Pub. L. 104–237 added subsec. (e).

EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104–237 not applicable to sale of any pseudoephedrine or phenylpropanolamine product prior to 12 months after Oct. 3, 1996, except that, on application of manufacturer of particular drug product, Attorney General may exercise sole and judicially unreviewable discretion to extend such effective date up to additional 6 months, see section 401(g) of Pub. L. 104–237, set out as a note under section 802 of this title.

EFFECTIVE DATE

Section effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as an Effective Date of 1993 Amendment note under section 802 of this title.

PART C—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

§ 821. Rules and regulations

The Attorney General is authorized to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and to listed chemicals.

(Pub. L. 91–513, title II, § 301, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 103–200, § 3(a), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 108–447, div. B, title VI, § 633(b), Dec. 8, 2004, 118 Stat. 2922.)

AMENDMENTS

2004—Pub. L. 108–447 substituted ''listed chemicals'' for ''the registration and control of regulated persons and of regulated transactions''.

1993—Pub. L. 103–200 inserted before period at end ''and to the registration and control of regulated persons and of regulated transactions''.

EFFECTIVE DATE OF 1993 AMENDMENT

Amendment by Pub. L. 103–200 effective on date that is 120 days after Dec. 17, 1993, see section 11 of Pub. L. 103–200, set out as a note under section 802 of this title.

§ 822. Persons required to register

(a) Period of registration

(1) Every person who manufactures or distributes any controlled substance or list I chemical, or who proposes to engage in the manufacture or distribution of any controlled substance or list I chemical, shall obtain annually a registration issued by the Attorney General in accordance with the rules and regulations promulgated by him.

(2) Every person who dispenses, or who proposes to dispense, any controlled substance, shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him. The Attorney General shall, by regulation, determine the period of such registrations. In no event, however, shall such registrations be issued for less than one year nor for more than three years.

(b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

(c) Exceptions

The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

(3) An ultimate user who possesses such substance for a purpose specified in section 802(25)[1] of this title.

(d) Waiver

The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers, distributors, or dispensers if he finds it consistent with the public health and safety.

(e) Separate registration

A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals.

(f) Inspection

The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him.

(g) Delivery of controlled substances by ultimate users for disposal

(1) An ultimate user who has lawfully obtained a controlled substance in accordance with this subchapter may, without being registered, deliver the controlled substance to another person for the purpose of disposal of the controlled substance if—

(A) the person receiving the controlled substance is authorized under this subchapter to engage in such activity; and

(B) the disposal takes place in accordance with regulations issued by the Attorney General to prevent diversion of controlled substances.

(2) In developing regulations under this subsection, the Attorney General shall take into consideration the public health and safety, as well as the ease and cost of program implementation and participation by various communities. Such regulations may not require any entity to establish or operate a delivery or disposal program.

(3) The Attorney General may, by regulation, authorize long-term care facilities, as defined by the Attorney General by regulation, to dispose of controlled substances on behalf of ultimate users who reside, or have resided, at such long-term care facilities in a manner that the Attorney General determines will provide effective controls against diversion and be consistent with the public health and safety.

(4) If a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided in paragraph (1) for an ultimate user.

(Pub. L. 91–513, title II, § 302, Oct. 27, 1970, 84 Stat. 1253; Pub. L. 98–473, title II, § 510, Oct. 12, 1984, 98 Stat. 2072; Pub. L. 103–200, § 3(b), Dec. 17, 1993, 107 Stat. 2336; Pub. L. 111–273, § 3(a), Oct. 12, 2010, 124 Stat. 2859.)

REFERENCES IN TEXT

This subchapter, referred to in subsecs. (b), (c), and (g)(1), was in the original ''this title'', meaning title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242, and is popularly known as the ''Controlled Substances Act''. For complete classification of title II to the Code, see second paragraph of Short Title note set out under section 801 of this title and Tables.

Section 802(25) of this title, referred to in subsec. (c)(3), was redesignated section 802(26) of this title by Pub. L. 98–473, title II, § 507(a), Oct. 12, 1984, 98 Stat. 2071, and was further redesignated section 802(27) of this title by Pub. L. 99–570, title I, § 1003(b)(2), Oct. 27, 1986, 100 Stat. 3207–6.

AMENDMENTS

2010—Subsec. (g). Pub. L. 111–273 added subsec. (g).

1993—Subsec. (a)(1). Pub. L. 103–200, § 3(b)(1), inserted ''or list I chemical'' after ''controlled substance'' in two places.

Subsec. (b). Pub. L. 103–200, § 3(b)(2), inserted ''or list I chemicals'' after ''controlled substances'' and ''or chemicals'' after ''such substances''.

Subsec. (c). Pub. L. 103–200, § 3(b)(3), inserted ''or list I chemical'' after ''controlled substance'' wherever appearing.

[1] See References in Text note below.