

(2) The known efficacy or usefulness of the substance for the marketed, advertised, or labeled purpose.

(3) The difference between the price at which the substance is sold and the price at which the substance it is purported to be or advertised as is normally sold.

(4) The diversion of the substance from legitimate channels and the clandestine importation, manufacture, or distribution of the substance.

(5) Whether the defendant knew or should have known the substance was intended to be consumed by injection, inhalation, ingestion, or any other immediate means.

(6) Any controlled substance analogue that is manufactured, formulated, sold, distributed, or marketed with the intent to avoid the provisions of existing drug laws.

### (c) Limitation

For purposes of this section, evidence that a substance was not marketed, advertised, or labeled for human consumption, by itself, shall not be sufficient to establish that the substance was not intended for human consumption.

(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; Pub. L. 115-271, title III, §3241, Oct. 24, 2018, 132 Stat. 3950.)

### Editorial Notes

#### REFERENCES IN TEXT

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

#### AMENDMENTS

2018—Pub. L. 115-271 designated existing provisions as subsec. (a), inserted heading, and added subsecs. (b) and (c).

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), 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) 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), 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) 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) 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) 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) 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.)

#### Editorial Notes

##### 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 phenylpropranolamine 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).

#### Statutory Notes and Related Subsidiaries

##### EFFECTIVE DATE OF 1996 AMENDMENT

Amendment by Pub. L. 104-237 not applicable to sale of any pseudoephedrine or phenylpropranolamine 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.)

#### Editorial Notes

##### 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”.

#### Statutory Notes and Related Subsidiaries

##### 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.

##### EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, see section 704 of

Pub. L. 91-513, set out as a note under section 801 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.

(3)(A) Except as provided in subparagraph (C), the registration of any registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals terminates if and when such registrant—

- (i) dies;
- (ii) ceases legal existence;
- (iii) discontinues business or professional practice; or
- (iv) surrenders such registration.

(B) In the case of such a registrant who ceases legal existence or discontinues business or professional practice, such registrant shall promptly notify the Attorney General in writing of such fact.

(C) No registration under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals, and no authority conferred thereby, may be assigned or otherwise transferred except upon such conditions as the Attorney General may specify and then only pursuant to written consent. A registrant to whom a registration is assigned or transferred pursuant to the preceding sentence may not manufacture, distribute, or dispense controlled substances or list I chemicals pursuant to such registration until the Attorney General receives such written consent.

(D) In the case of a registrant under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals desiring to discontinue business or professional practice altogether or with respect to controlled substances and list I chemicals (without assigning or transferring such business or professional practice to another entity), such registrant shall return to the Attorney General for cancellation—

- (i) the registrant's certificate of registration;
- (ii) any unexecuted order forms in the registrant's possession; and
- (iii) any other documentation that the Attorney General may require.

#### (b) Authorized activities

Persons registered by the Attorney General under this subchapter to manufacture, dis-