

(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 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).

#### Statutory Notes and Related Subsidiaries

##### 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.)

#### 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;