

“(ix) the effectiveness of cross-agency collaboration between [the] Department of Health and Human Services and the Drug Enforcement Administration for expanding effective opioid use disorder treatment.”

PROVISIONAL REGISTRATION

For provisional registration of persons engaged in manufacturing, distributing, or dispensing of controlled substances on the day before the effective date of section 822 of this title who are registered on such date under section 360 of this title or section 4722 of Title 26, Internal Revenue Code, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.

**§ 824. Denial, revocation, or suspension of registration**

**(a) Grounds**

A registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—

- (1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II;
- (2) has been convicted of a felony under this subchapter or subchapter II or any other law of the United States, or of any State, relating to any substance defined in this subchapter as a controlled substance or a list I chemical;
- (3) has had his State license or registration suspended, revoked, or denied by competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or list I chemicals or has had the suspension, revocation, or denial of his registration recommended by competent State authority;
- (4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section; or
- (5) has been excluded (or directed to be excluded) from participation in a program pursuant to section 1320a-7(a) of title 42.

A registration pursuant to section 823(g)(1) of this title to dispense a narcotic drug for maintenance treatment or detoxification treatment may be suspended or revoked by the Attorney General upon a finding that the registrant has failed to comply with any standard referred to in section 823(g)(1) of this title.

**(b) Limits of revocation or suspension**

The Attorney General may limit revocation or suspension of a registration to the particular controlled substance or list I chemical with respect to which grounds for revocation or suspension exist.

**(c) Service of show cause order; proceedings**

(1) Before taking action pursuant to this section, or pursuant to a denial of registration under section 823 of this title, the Attorney General shall serve upon the applicant or registrant an order to show cause why registration should not be denied, revoked, or suspended.

(2) An order to show cause under paragraph (1) shall—

- (A) contain a statement of the basis for the denial, revocation, or suspension, including

specific citations to any laws or regulations alleged to be violated by the applicant or registrant;

(B) direct the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but not less than 30 days after the date of receipt of the order; and

(C) notify the applicant or registrant of the opportunity to submit a corrective action plan on or before the date of appearance.

(3) Upon review of any corrective action plan submitted by an applicant or registrant pursuant to paragraph (2), the Attorney General shall determine whether denial, revocation, or suspension proceedings should be discontinued, or deferred for the purposes of modification, amendment, or clarification to such plan.

(4) Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States.

(5) The requirements of this subsection shall not apply to the issuance of an immediate suspension order under subsection (d).

**(d) Suspension of registration in cases of imminent danger**

(1) The Attorney General may, in his discretion, suspend any registration simultaneously with the institution of proceedings under this section, in cases where he finds that there is an imminent danger to the public health or safety. A failure to comply with a standard referred to in section 823(g)(1) of this title may be treated under this subsection as grounds for immediate suspension of a registration granted under such section. A suspension under this subsection shall continue in effect until the conclusion of such proceedings, including judicial review thereof, unless sooner withdrawn by the Attorney General or dissolved by a court of competent jurisdiction.

(2) In this subsection, the phrase “imminent danger to the public health or safety” means that, due to the failure of the registrant to maintain effective controls against diversion or otherwise comply with the obligations of a registrant under this subchapter or subchapter II, there is a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration.

**(e) Suspension and revocation of quotas**

The suspension or revocation of a registration under this section shall operate to suspend or revoke any quota applicable under section 826 of this title.

**(f) Disposition of controlled substances or list I chemicals**

In the event the Attorney General suspends or revokes a registration granted under section 823 of this title, all controlled substances or list I chemicals owned or possessed by the registrant pursuant to such registration at the time of suspension or the effective date of the revocation

order, as the case may be, may, in the discretion of the Attorney General, be placed under seal. No disposition may be made of any controlled substances or list I chemicals under seal until the time for taking an appeal has elapsed or until all appeals have been concluded except that a court, upon application therefor, may at any time order the sale of perishable controlled substances or list I chemicals. Any such order shall require the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all such controlled substances or list I chemicals (or proceeds of sale deposited in court) shall be forfeited to the United States; and the Attorney General shall dispose of such controlled substances or list I chemicals in accordance with section 881(e) of this title. All right, title, and interest in such controlled substances or list I chemicals shall vest in the United States upon a revocation order becoming final.

**(g) Seizure or placement under seal of controlled substances or list I chemicals**

The Attorney General may, in his discretion, seize or place under seal any controlled substances or list I chemicals owned or possessed by a registrant whose registration has expired or who has ceased to practice or do business in the manner contemplated by his registration. Such controlled substances or list I chemicals shall be held for the benefit of the registrant, or his successor in interest. The Attorney General shall notify a registrant, or his successor in interest, who has any controlled substance or list I chemical seized or placed under seal of the procedures to be followed to secure the return of the controlled substance or list I chemical and the conditions under which it will be returned. The Attorney General may not dispose of any controlled substance or list I chemical seized or placed under seal under this subsection until the expiration of one hundred and eighty days from the date such substance or chemical was seized or placed under seal.

(Pub. L. 91-513, title II, §304, Oct. 27, 1970, 84 Stat. 1255; Pub. L. 93-281, §4, May 14, 1974, 88 Stat. 125; Pub. L. 98-473, title II, §§304, 512, 513, Oct. 12, 1984, 98 Stat. 2050, 2073; Pub. L. 100-93, §8(j), Aug. 18, 1987, 101 Stat. 695; Pub. L. 103-200, §3(d), Dec. 17, 1993, 107 Stat. 2337; Pub. L. 103-322, title XXXIII, §330024(e), Sept. 13, 1994, 108 Stat. 2151; Pub. L. 106-310, div. B, title XXXV, §3502(b), Oct. 17, 2000, 114 Stat. 1227; Pub. L. 114-145, §2(a)(2), (b), Apr. 19, 2016, 130 Stat. 354.)

REFERENCES IN TEXT

This subchapter, referred to in subssecs. (a)(1), (2), (c)(4), and (d)(2), was in the original "this title", meaning title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, 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.

Subchapter II, referred to in subssecs. (a)(1), (2) and (d)(2), was in the original "title III", meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285. Part A of title III comprises subchapter II of this chapter. For classification of Part B, consisting of sections 1101 to 1105 of title III, see Tables.

AMENDMENTS

2016—Subsec. (c). Pub. L. 114-145, §2(b), struck out "The order to show cause shall contain a statement of

the basis thereof and shall call upon the applicant or registrant to appear before the Attorney General at a time and place stated in the order, but in no event less than thirty days after the date of receipt of the order. Proceedings to deny, revoke, or suspend shall be conducted pursuant to this section in accordance with subchapter II of chapter 5 of title 5. Such proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter or any other law of the United States." after "denied, revoked, or suspended.", designated existing provisions as par. (1), and added pars. (2) to (5).

Subsec. (d). Pub. L. 114-145, §2(a)(2), designated existing provisions as par. (1) and added par. (2).

2000—Subsec. (a). Pub. L. 106-310, §3502(b)(1), substituted "section 823(g)(1) of this title" for "section 823(g) of this title" in two places in concluding provisions.

Subsec. (d). Pub. L. 106-310, §3502(b)(2), substituted "section 823(g)(1) of this title" for "section 823(g) of this title".

1994—Subsec. (g). Pub. L. 103-322 inserted "or chemical" after "such substance" in last sentence.

1993—Subsec. (a). Pub. L. 103-200, §3(d)(1), inserted "or a list I chemical" after "controlled substance" in introductory provisions and par. (2) and inserted "or list I chemicals" after "controlled substances" in par. (3).

Subsec. (b). Pub. L. 103-200, §3(d)(2), inserted "or list I chemical" after "controlled substance".

Subsec. (f). Pub. L. 103-200, §3(d)(3), inserted "or list I chemicals" after "controlled substances" wherever appearing.

Subsec. (g). Pub. L. 103-200, §3(d)(4), inserted "or list I chemicals" after "controlled substances" in two places and "or list I chemical" after "controlled substance" wherever appearing.

1987—Subsec. (a)(5). Pub. L. 100-93 added par. (5).

1984—Subsec. (a)(3). Pub. L. 98-473, §512(1), inserted provisions relating to suspension, etc., recommended by competent State authority.

Subsec. (a)(4). Pub. L. 98-473, §512(2), added par. (4).

Subsec. (f). Pub. L. 98-473, §304, inserted provisions relating to vesting of right, title, and interest in the United States.

Subsec. (g). Pub. L. 98-473, §513, added subsec. (g).

1974—Subsec. (a). Pub. L. 93-281, §4(a), provided for revocation or suspension of a registration pursuant to section 823(g) of this title for failure of a registrant to comply with standards referred to in such section 823(g).

Subsec. (d). Pub. L. 93-281, §4(b), substituted "A suspension under this subsection" for "Such suspension" in third sentence.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103-322 effective 120 days after Dec. 17, 1993, see section 330024(f) of Pub. L. 103-322, set out as a note under section 802 of this title.

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 OF 1987 AMENDMENT

Amendment by Pub. L. 100-93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100-93, set out as a note under section 1320a-7 of Title 42, The Public Health and Welfare.

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.

## PROVISIONAL REGISTRATION

Applicability of this section to provisional registrations, see section 703 of Pub. L. 91-513, set out as a note under section 822 of this title.

**§ 825. Labeling and packaging****(a) Symbol**

It shall be unlawful to distribute a controlled substance in a commercial container unless such container, when and as required by regulations of the Attorney General, bears a label (as defined in section 321(k) of this title) containing an identifying symbol for such substance in accordance with such regulations. A different symbol shall be required for each schedule of controlled substances.

**(b) Unlawful distribution without identifying symbol**

It shall be unlawful for the manufacturer of any controlled substance to distribute such substance unless the labeling (as defined in section 321(m) of this title) of such substance contains, when and as required by regulations of the Attorney General, the identifying symbol required under subsection (a).

**(c) Warning on label**

The Secretary shall prescribe regulations under section 353(b) of this title which shall provide that the label of a drug listed in schedule II, III, or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a crime to transfer the drug to any person other than the patient.

**(d) Containers to be securely sealed**

It shall be unlawful to distribute controlled substances in schedule I or II, and narcotic drugs in schedule III or IV, unless the bottle or other container, stopper, covering, or wrapper thereof is securely sealed as required by regulations of the Attorney General.

**(e) False labeling of anabolic steroids**

(1) It shall be unlawful to import, export, manufacture, distribute, dispense, or possess with intent to manufacture, distribute, or dispense, an anabolic steroid or product containing an anabolic steroid, unless the steroid or product bears a label clearly identifying an anabolic steroid or product containing an anabolic steroid by the nomenclature used by the International Union of Pure and Applied Chemistry (IUPAC).

(2)(A) A product described in subparagraph (B) is exempt from the International Union of Pure and Applied Chemistry nomenclature requirement of this subsection if such product is labeled in the manner required under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(B) A product is described in this subparagraph if the product—

(i) is the subject of an approved application as described in section 505(b) or (j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(b), (j)]; or

(ii) is exempt from the provisions of section 505 of such Act relating to new drugs because—

(I) it is intended solely for investigational use as described in section 505(i) of such Act; and

(II) such product is being used exclusively for purposes of a clinical trial that is the subject of an effective investigational new drug application.

(Pub. L. 91-513, title II, §305, Oct. 27, 1970, 84 Stat. 1256; Pub. L. 113-260, §3(a), Dec. 18, 2014, 128 Stat. 2931.)

## REFERENCES IN TEXT

Schedules I, II, III, and IV, referred to in subsecs. (c) and (d), are set out in section 812(c) of this title.

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(2)(A), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

## AMENDMENTS

2014—Subsec. (e). Pub. L. 113-260 added subsec. (e).

## EFFECTIVE DATE

Section effective on first day of seventh calendar month that begins after Oct. 26, 1970, but with Attorney General authorized to postpone such effective date for such period as he might determine to be necessary for the efficient administration of this subchapter, see section 704(c) of Pub. L. 91-513, set out as a note under section 801 of this title.

## IDENTIFICATION AND PUBLICATION OF LIST OF PRODUCTS CONTAINING ANABOLIC STEROIDS

Pub. L. 113-260, §4, Dec. 18, 2014, 128 Stat. 2932, provided that:

“(a) IN GENERAL.—The Attorney General may, in the Attorney General’s discretion, collect data and analyze products to determine whether they contain anabolic steroids and are properly labeled in accordance with this Act [see section 1 of Pub. L. 113-260, set out as a Short Title of 2014 Amendment note under section 801 of this title] and the amendments made by this Act. The Attorney General may publish in the Federal Register or on the website of the Drug Enforcement Administration a list of products which the Attorney General has determined, based on substantial evidence, contain an anabolic steroid and are not labeled in accordance with this Act and the amendments made by this Act.

“(b) ABSENCE FROM LIST.—The absence of a product from the list referred to in subsection (a) shall not constitute evidence that the product does not contain an anabolic steroid.”

**§ 826. Production quotas for controlled substances****(a) Establishment of total annual needs**

(1) The Attorney General shall determine the total quantity and establish production quotas for each basic class of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each calendar year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Except as provided in paragraph (2), production quotas shall be established in terms of quantities of each basic class of controlled substance and not in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance.

(2) The Attorney General may, if the Attorney General determines it will assist in avoiding the