Subsec. (g)(2)(J)(iii). Pub. L. 109–469, § 1102(2)(C), substituted ''subparagraph (B)(iii) should be applied by limiting the total number of patients a practitioner may treat to 30, then the provisions in such subparagraph (B)(iii) permitting more than 30 patients shall not apply, effective'' for ''this paragraph should not remain in effect, this paragraph ceases to be in effect''.

Subsec. (h). Pub. L. 109–177 substituted ''clause (iv) or (v) of section 802(39)(A) of this title'' for ''section 802(39)(A)(iv) of this title'' in introductory provisions.

2005—Subsec. (g)(2)(B)(iii). Pub. L. 109–56, § 1(b), substituted ''The total'' for ''In any case in which the practitioner is not in a group practice, the total''.

Subsec. (g)(2)(B)(iv). Pub. L. 109–56, § 1(a), struck out cl. (iv) which read as follows: ''In any case in which the practitioner is in a group practice, the total number of such patients of the group practice at any one time will not exceed the applicable number. For purposes of this clause, the applicable number is 30, except that the Secretary may by regulation change such total number, and the Secretary for such purposes may by regulation establish different categories on the basis of the number of practitioners in a group practice and establish for the various categories different numerical limitations on the number of such patients that the group practice may have.''

2002—Subsec. (g)(2)(I). Pub. L. 107–273, § 2501(1), which directed the substitution of ''on the date of approval by the Food and Drug Administration of a drug in schedule III, IV, or V, a State may not preclude a practitioner from dispensing or prescribing such drug, or combination of such drugs,'' for ''on October 17, 2000, a State may not preclude a practitioner from dispensing or prescribing drugs in schedule III, IV, or V, or combinations of such drugs,'', was executed by making the substitution for the phrase which in the original began with ''on the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''on October 17, 2000,'' to reflect the probable intent of Congress.

Subsec. (g)(2)(J)(i). Pub. L. 107–273, § 2501(2), which directed the substitution of ''the date referred to in subparagraph (I),'' for ''October 17, 2000,'' was executed by making the substitution for text which in the original read ''the date of the enactment of the Drug Addiction Treatment Act of 2000,'' rather than the editorial translation ''October 17, 2000,'' to reflect the probable intent of Congress.

2000—Subsec. (g). Pub. L. 106–310 designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), practitioners who dispense'' for ''Practitioners who dispense'', redesignated former pars. (1) to (3) as subpars. (A) to (C), respectively, of par. (1) and redesignated former subpars. (A) and (B) of former par. (2) as cls. (i) and (ii), respectively, of subpar. (B) of par. (1), and added par. (2).

1993—Subsec. (h). Pub. L. 103–200 added subsec. (h).

1984—Subsec. (f). Pub. L. 98–473 amended subsec. (f) generally, substituting provisions relating to registration authority of Attorney General respecting dispensation or conduct of research with controlled research, and separate authority of Secretary respecting registration, for provisions relating to general registration requirements respecting dispensation or conduct of research with controlled or nonnarcotic controlled substances.

1978—Subsec. (f). Pub. L. 95–633 inserted provision relating to the construction of the Convention on Psychotropic Substances.

1974—Subsec. (g). Pub. L. 93–281 added subsec. (g).

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by Pub. L. 110–425 effective 180 days after Oct. 15, 2008, except as otherwise provided, see section 3(j) of Pub. L. 110–425, set out as a note under section 802 of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–56, § 1(c), Aug. 2, 2005, 119 Stat. 591, provided that: ''This section [amending this section] shall take effect on the date of enactment of this Act [Aug. 2, 2005].''

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 1978 AMENDMENT

Amendment by Pub. L. 95–633 effective on date the Convention on Psychotropic Substances enters into force in the United States [July 15, 1980], see section 112 of Pub. L. 95–633, set out as an Effective Date note under section 801a of this title.

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 of this chapter;

(2) has been convicted of a felony under this subchapter or subchapter II of this chapter 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

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. 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.

(d) Suspension of registration in cases of imminent danger

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.

(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.)

REFERENCES IN TEXT

This subchapter, referred to in subsec. (a)(1), (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 of this chapter, referred to in subsec. (a)(1), (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

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.

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) of this section.

(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.

(Pub. L. 91–513, title II, § 305, Oct. 27, 1970, 84 Stat. 1256.)

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.

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.

§ 826. Production quotas for controlled substances

(a) Establishment of total annual needs

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. 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.

(b) Individual production quotas; revised quotas

The Attorney General shall limit or reduce individual production quotas to the extent necessary to prevent the aggregate of individual quotas from exceeding the amount determined necessary each year by the Attorney General under subsection (a) of this section. The quota of each registered manufacturer for each basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine shall be revised in the same proportion as the limitation or reduction of the aggregate of the quotas. However, if any registrant, before the issuance of a limitation or reduction in quota, has manufactured in excess of his revised quota, the amount of the excess shall be subtracted from his quota for the following year.

(c) Manufacturing quotas for registered manufacturers

On or before October 1 of each year, upon application therefor by a registered manufacturer, the Attorney General shall fix a manufacturing quota for the basic classes of controlled substances in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine that the manufacturer seeks to produce. The quota shall be subject to the provisions of subsections (a) and (b) of this section. In fixing such quotas, the Attorney General shall determine the manufacturer's estimated disposal, inventory, and other requirements for the calendar year; and, in making his determination, the Attorney General shall consider the manufacturer's current rate of disposal, the trend of the national disposal rate during the preceding calendar year,