

§ 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 in-

dustrial 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, the manufacturer's production cycle and inventory position, the economic availability of raw materials, yield and stability problems, emergencies such as strikes and fires, and other factors.

(d) Quotas for registrants who have not manufactured controlled substance during one or more preceding years

The Attorney General shall, upon application and subject to the provisions of subsections (a) and (b) of this section, fix a quota for a basic class of controlled substance in schedule I or II for any registrant who has not manufactured that basic class of controlled substance or ephedrine, pseudoephedrine, or phenylpropanolamine during one or more preceding calendar years. In fixing such quota, the Attorney General shall take into account the registrant's reasonably anticipated requirements for the current year; and, in making his determination of such requirements, he shall consider such factors specified in subsection (c) of this section as may be relevant.

(e) Quota increases

At any time during the year any registrant who has applied for or received a manufacturing

quota for a basic class of controlled substance in schedule I or II or for ephedrine, pseudoephedrine, or phenylpropanolamine may apply for an increase in that quota to meet his estimated disposal, inventory, and other requirements during the remainder of that year. In passing upon the application the Attorney General shall take into consideration any occurrences since the filing of the registrant's initial quota application that may require an increased manufacturing rate by the registrant during the balance of the year. In passing upon the application the Attorney General may also take into account the amount, if any, by which the determination of the Attorney General under subsection (a) of this section exceeds the aggregate of the quotas of all registrants under this section.

(f) Incidental production exception

Notwithstanding any other provisions of this subchapter, no registration or quota may be required for the manufacture of such quantities of controlled substances in schedules I and II or ephedrine, pseudoephedrine, or phenylpropanolamine as incidentally and necessarily result from the manufacturing process used for the manufacture of a controlled substance or of ephedrine, pseudoephedrine, or phenylpropanolamine with respect to which its manufacturer is duly registered under this subchapter. The Attorney General may, by regulation, prescribe restrictions on the retention and disposal of such incidentally produced substances or chemicals.

(g) Reference to ephedrine, pseudoephedrine, or phenylpropanolamine

Each reference in this section to ephedrine, pseudoephedrine, or phenylpropanolamine includes each of the salts, optical isomers, and salts of optical isomers of such chemical.

(h) Quotas applicable to drugs in shortage

(1) Not later than 30 days after the receipt of a request described in paragraph (2), the Attorney General shall—

(A) complete review of such request; and

(B)(i) as necessary to address a shortage of a controlled substance, increase the aggregate and individual production quotas under this section applicable to such controlled substance and any ingredient therein to the level requested; or

(ii) if the Attorney General determines that the level requested is not necessary to address a shortage of a controlled substance, the Attorney General shall provide a written response detailing the basis for the Attorney General's determination.

The Secretary shall make the written response provided under subparagraph (B)(ii) available to the public on the Internet Web site of the Food and Drug Administration.

(2) A request is described in this paragraph if—

(A) the request pertains to a controlled substance on the list of drugs in shortage maintained under section 356e of this title;

(B) the request is submitted by the manufacturer of the controlled substance; and

(C) the controlled substance is in schedule II.

(Pub. L. 91-513, title II, §306, Oct. 27, 1970, 84 Stat. 1257; Pub. L. 94-273, §3(16), Apr. 21, 1976, 90

Stat. 377; Pub. L. 109-177, title VII, §713, Mar. 9, 2006, 120 Stat. 264; Pub. L. 112-144, title X, §1005, July 9, 2012, 126 Stat. 1105.)

REFERENCES IN TEXT

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

AMENDMENTS

2012—Subsec. (h). Pub. L. 112-144 added subsec. (h).
 2006—Subsec. (a). Pub. L. 109-177, §713(1), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for each basic class of controlled substance in schedules I and II”.

Subsec. (b). Pub. L. 109-177, §713(2), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine” after “for each basic class of controlled substance in schedule I or II”.

Subsec. (c). Pub. L. 109-177, §713(3), inserted “and for ephedrine, pseudoephedrine, and phenylpropanolamine” after “for the basic classes of controlled substances in schedules I and II”.

Subsec. (d). Pub. L. 109-177, §713(4), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “that basic class of controlled substance”.

Subsec. (e). Pub. L. 109-177, §713(5), inserted “or for ephedrine, pseudoephedrine, or phenylpropanolamine” after “for a basic class of controlled substance in schedule I or II”.

Subsec. (f). Pub. L. 109-177, §713(6), inserted “or ephedrine, pseudoephedrine, or phenylpropanolamine” after “controlled substances in schedules I and II”, “or of ephedrine, pseudoephedrine, or phenylpropanolamine” after “the manufacture of a controlled substance”, and “or chemicals” after “such incidentally produced substances”.

Subsec. (g). Pub. L. 109-177, §713(7), added subsec. (g).
 1976—Subsec. (c). Pub. L. 94-273 substituted “October” for “July”.

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.

COORDINATION WITH UNITED STATES TRADE REPRESENTATIVE

Pub. L. 109-177, title VII, §718, Mar. 9, 2006, 120 Stat. 267, provided that: “In implementing sections 713 through 717 and section 721 of this title [amending this section and sections 830, 842, 952, 960, and 971 of this title], the Attorney General shall consult with the United States Trade Representative to ensure implementation complies with all applicable international treaties and obligations of the United States.”

§ 826a. Attorney General report on drug shortages

Not later than 6 months after July 9, 2012, and annually thereafter, the Attorney General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages that—

- (1) identifies the number of requests received under section 826(h) of this title (as added by section 1005 of this Act), the average review time for such requests, the number of requests granted and denied under such section, and, for each of the requests denied under such section, the basis for such denial;
- (2) describes the coordination between the Drug Enforcement Administration and Food

and Drug Administration on efforts to prevent or alleviate drug shortages; and

- (3) identifies drugs containing a controlled substance subject to section 826 of this title when such a drug is determined by the Secretary to be in shortage.

(Pub. L. 112-144, title X, §1006, July 9, 2012, 126 Stat. 1105.)

REFERENCES IN TEXT

Section 1005 of this Act, referred to in par. (1), means section 1005 of Pub. L. 112-144, which amended section 826 of this title.

CODIFICATION

Section was enacted as part of the Food and Drug Administration Safety and Innovation Act, and not as part of the Controlled Substances Act which comprises this subchapter.

DEFINITION OF “SECRETARY”

The term “Secretary” as meaning the Secretary of Health and Human Services, see section 1001(b) of Pub. L. 112-144, set out as an Effect of Notification note under section 356c of this title.

§ 827. Records and reports of registrants

(a) Inventory

Except as provided in subsection (c) of this section—

- (1) every registrant under this subchapter shall, on May 1, 1971, or as soon thereafter as such registrant first engages in the manufacture, distribution, or dispensing of controlled substances, and every second year thereafter, make a complete and accurate record of all stocks thereof on hand, except that the regulations prescribed under this section shall permit each such biennial inventory (following the initial inventory required by this paragraph) to be prepared on such registrant’s regular general physical inventory date (if any) which is nearest to and does not vary by more than six months from the biennial date that would otherwise apply;
- (2) on the effective date of each regulation of the Attorney General controlling a substance that immediately prior to such date was not a controlled substance, each registrant under this subchapter manufacturing, distributing, or dispensing such substance shall make a complete and accurate record of all stocks thereof on hand; and

- (3) on and after May 1, 1971, every registrant under this subchapter manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him, except that this paragraph shall not require the maintenance of a perpetual inventory.

(b) Availability of records

Every inventory or other record required under this section (1) shall be in accordance with, and contain such relevant information as may be required by, regulations of the Attorney General, (2) shall (A) be maintained separately from all other records of the registrant, or (B) alternatively, in the case of nonnarcotic con-