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

overproduction, shortages, or diversion of a controlled substance, establish an aggregate or individual production quota under this subsection, or a procurement quota established by the Attorney General by regulation, in terms of pharmaceutical dosage forms prepared from or containing the controlled substance.

(b) Individual manufacturing quotas; revised quotas

The Attorney General shall limit or reduce individual manufacturing 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). 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 December 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.

(i) Strengthening considerations for DEA opioid quotas

(1)(A) In establishing any quota under this section, or any procurement quota established by the Attorney General by regulation, for fentanyl, oxycodone, hydrocodone, oxymorphone, or hydromorphone (in this subsection referred to as a ''covered controlled substance''), the Attorney General shall estimate the amount of diversion of the covered controlled substance that occurs in the United States.

(B) In estimating diversion under this paragraph, the Attorney General—

(i) shall consider information the Attorney General, in consultation with the Secretary of Health and Human Services, determines reliable on rates of overdose deaths and abuse and overall public health impact related to the covered controlled substance in the United States; and

(ii) may take into consideration whatever other sources of information the Attorney General determines reliable.

(C) After estimating the amount of diversion of a covered controlled substance, the Attorney General shall make appropriate quota reductions, as determined by the Attorney General, from the quota the Attorney General would have otherwise established had such diversion not been considered.

(2)(A) For any year for which the approved aggregate production quota for a covered controlled substance is higher than the approved aggregate production quota for the covered controlled substance for the previous year, the Attorney General, in consultation with the Secretary of Health and Human Services, shall include in the final order an explanation of why the public health benefits of increasing the quota clearly outweigh the consequences of having an increased volume of the covered controlled substance available for sale, and potential diversion, in the United States.

(B) Not later than 1 year after October 24, 2018, and every year thereafter, the Attorney General shall submit to the Committee on the Judiciary, the Committee on Health, Education, Labor, and Pensions, and the Committee on Appropriations of the Senate and the Committee on the Judiciary, the Committee on Energy and Commerce, and the Committee on Appropriations of the House of Representatives the following information with regard to each covered controlled substance:

(i) An anonymized count of the total number of manufacturers issued individual manufacturing quotas that year for the covered controlled substance.

(ii) An anonymized count of how many such manufacturers were issued an approved manufacturing quota that was higher than the quota issued to that manufacturer for the covered controlled substance in the previous year.

(3) Not later than 1 year after October 24, 2018, the Attorney General shall submit to Congress a report on how the Attorney General, when fixing and adjusting production and manufacturing quotas under this section for covered controlled substances, will—

(A) take into consideration changes in the accepted medical use of the covered controlled substances; and

(B) work with the Secretary of Health and Human Services on methods to appropriately and anonymously estimate the type and amount of covered controlled substances that are submitted for collection from approved drug collection receptacles, mail-back programs, and take-back events.

(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; Pub. L. 115–271, title III, § 3282(a), Oct. 24, 2018, 132 Stat. 3954.)

REFERENCES IN TEXT

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

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–271, § 3282(a)(1), designated existing provisions as par. (1), substituted ''Except as provided in paragraph (2), production'' for ''Production'' in second sentence, and added par. (2).

Subsec. (b). Pub. L. 115–271, § 3282(a)(2), substituted ''reduce individual manufacturing'' for ''reduce individual production''.

Subsec. (c). Pub. L. 115–271, § 3282(a)(3), substituted ''December'' for ''October''.

Subsec. (i). Pub. L. 115–271, § 3282(a)(4), added subsec. (i).

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.

CHANGE TO EDITORIAL HEADING IN UNITED STATES CODE

Pub. L. 115–271, title III, § 3282(b), Oct. 24, 2018, 132 Stat. 3955, provided that: ''The Law Revision Counsel is

directed to amend the heading for subsection (b) of section 826 of title 21, United States Code, by striking 'Production' and inserting 'Manufacturing'.''

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)—

(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 controlled substances, be in such form that information required by the Attorney General is readily retrievable from the ordinary business records of the registrant, and (3) shall be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General.

(c) Nonapplicability

The foregoing provisions of this section shall not apply—

(1)(A) to the prescribing of controlled substances in schedule II, III, IV, or V by practitioners acting in the lawful course of their professional practice unless such substance is prescribed in the course of maintenance or detoxification treatment of an individual; or

(B) to the administering of a controlled substance in schedule II, III, IV, or V unless the practitioner regularly engages in the dispensing or administering of controlled substances and charges his patients, either separately or together with charges for other professional services, for substances so dispensed or administered or unless such substance is administered in the course of maintenance treatment or detoxification treatment of an individual;

(2)(A) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in research conducted in conformity with an exemption granted under section 355(i) or 360b(j) of this title;

(B) to the use of controlled substances, at establishments registered under this subchapter which keep records with respect to such substances, in preclinical research or in teaching; or

(3) to the extent of any exemption granted to any person, with respect to all or part of such provisions, by the Attorney General by or pur-