

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.

Statutory Notes and Related Subsidiaries

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.)

Editorial Notes

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).

Statutory Notes and Related Subsidiaries

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.