abolic 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

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). 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