

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 per-

mit 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