TITLE 21--FOOD AND DRUGS

CHAPTER 13--DRUG ABUSE PREVENTION AND CONTROL

SUBCHAPTER I--CONTROL AND ENFORCEMENT

Part C--Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances

Sec. 830. Regulation of listed chemicals and certain machines

(a) Record of regulated transactions

(1) Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction for two years after the date of the transaction.

(2) A record under this subsection shall be retrievable and shall include the date of the regulated transaction, the identity of each party to the regulated transaction, a statement of the quantity and form of the listed chemical, a description of the tableting machine or encapsulating machine, and a description of the method of transfer. Such record shall be available for inspection and copying by the Attorney General.

(3) It is the duty of each regulated person who engages in a regulated transaction to identify each other party to the transaction. It is the duty of such other party to present proof of identity to the regulated person. The Attorney General shall specify by regulation the types of documents and other evidence that constitute proof of identity for purposes of this paragraph.

(b) Reports to Attorney General

(1) Each regulated person shall report to the Attorney General, in such form and manner as the Attorney General shall prescribe by regulation--

(A) any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of this subchapter;

(B) any proposed regulated transaction with a person whose description or other identifying characteristic the Attorney General furnishes in advance to the regulated person;

(C) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person; and

(D) any regulated transaction in a tableting machine or an encapsulating machine.

Each report under subparagraph (A) shall be made at the earliest practicable opportunity after the regulated person becomes aware of the circumstance involved. A regulated person may not complete a transaction with a person whose description or identifying characteristic is furnished to the regulated person under subparagraph (B) unless the transaction is approved by the Attorney General. The Attorney General shall make available to regulated persons guidance documents describing transactions and circumstances for which reports are required under subparagraph (A) and subparagraph (C).

(2) A regulated person that manufactures a listed chemical shall report annually to the Attorney General, in such form and manner and containing such specific data as the Attorney General shall prescribe by regulation, information concerning listed chemicals manufactured by the person. The requirement of the preceding sentence shall not apply to the manufacture of a drug product that is exempted under section 802(39)(A)(iv) of this title.

(3) Mail order reporting.--(A) As used in this paragraph:

(i) The term ``drug product'' means an active ingredient in dosage form that has been approved or otherwise may be lawfully marketed under the Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] for distribution in the United States.

(ii) The term ``valid prescription'' means a prescription which is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

(B) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction which--

(i) involves ephedrine, pseudoephedrine, or phenylpropanolamine (including drug products containing these chemicals); and

(ii) uses or attempts to use the Postal Service or any private or commercial carrier;

shall, on a monthly basis, submit a report of each such transaction conducted during the previous month to the Attorney General in such form, containing such data, and at such times as the Attorney General shall establish by regulation.

(C) The data required for such reports shall include--

(i) the name of the purchaser;

(ii) the quantity and form of the ephedrine, pseudoephedrine, or phenylpropanolamine purchased; and

(iii) the address to which such ephedrine, pseudoephedrine, or phenylpropanolamine was sent.

(D) Except as provided in subparagraph (E), the following distributions to a nonregulated person, and the following export transactions, shall not be subject to the reporting requirement in subparagraph (B):

(i) Distributions of sample packages of drug products when such packages contain not more than two solid dosage units or the equivalent of two dosage units in liquid form, not to exceed 10 milliliters of liquid per package, and not more than one package is distributed to an individual or residential address in any 30-day period.

(ii) Distributions of drug products by retail distributors that

may not include face-to-face transactions to the extent that such distributions are consistent with the activities authorized for a retail distributor as specified in section 802(46) of this title.

(iii) Distributions of drug products to a resident of a long term care facility (as that term is defined in regulations prescribed by the Attorney General) or distributions of drug products to a long term care facility for dispensing to or for use by a resident of that facility.

(iv) Distributions of drug products pursuant to a valid prescription.

(v) Exports which have been reported to the Attorney General pursuant to section 954 or 971 of this title or which are subject to a waiver granted under section 971(e)(2) of this title.

(vi) Any quantity, method, or type of distribution or any quantity, method, or type of distribution of a specific listed chemical (including specific formulations or drug products) or of a group of listed chemicals (including specific formulations or drug products) which the Attorney General has excluded by regulation from such reporting requirement on the basis that such reporting is not necessary for the enforcement of this subchapter or subchapter II of this chapter.

(E) The Attorney General may revoke any or all of the exemptions listed in subparagraph (D) for an individual regulated person if he finds that drug products distributed by the regulated person are being used in violation of this subchapter or subchapter II of this chapter. The regulated person shall be notified of the revocation, which will be effective upon receipt by the person of such notice, as provided in section 971(c)(1) of this title, and shall have the right to an expedited hearing as provided in section 971(c)(2) of this title.

(c) Confidentiality of information obtained by Attorney General; non-disclosure; exceptions

(1) Except as provided in paragraph (2), any information obtained by the Attorney General under this section which is exempt from disclosure under section 552(a) of title 5, by reason of section 552(b)(4) of such title, is confidential and may not be disclosed to any person.

(2) Information referred to in paragraph (1) may be disclosed only--

(A) to an officer or employee of the United States engaged in carrying out this subchapter, subchapter II of this chapter, or the customs laws;

(B) when relevant in any investigation or proceeding for the enforcement of this subchapter, subchapter II of this chapter, or the customs laws;

(C) when necessary to comply with an obligation of the United States under a treaty or other international agreement; or

(D) to a State or local official or employee in conjunction with the enforcement of controlled substances laws or chemical control laws.

(3) The Attorney General shall--

(A) take such action as may be necessary to prevent unauthorized disclosure of information by any person to whom such information is disclosed under paragraph (2); and

(B) issue guidelines that limit, to the maximum extent feasible, the disclosure of proprietary business information, including the

names or identities of United States exporters of listed chemicals, to any person to whom such information is disclosed under paragraph (2).

(4) Any person who is aggrieved by a disclosure of information in violation of this section may bring a civil action against the violator for appropriate relief.

(5) Notwithstanding paragraph (4), a civil action may not be brought under such paragraph against investigative or law enforcement personnel of the Drug Enforcement Administration.

(Pub. L. 91-513, title II, Sec. 310, as added Pub. L. 95-633, title II, Sec. 202(a), Nov. 10, 1978, 92 Stat. 3774; amended Pub. L. 100-690, title VI, Sec. 6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub. L. 103-200, Secs. 2(c), 10, Dec. 17, 1993, 107 Stat. 2336, 2341; Pub. L. 104-237, title II, Sec. 208, title IV, Sec. 402, Oct. 3, 1996, 110 Stat. 3104, 3111; Pub. L. 106-310, div. B, title XXXVI, Sec. 3652, Oct. 17, 2000, 114 Stat. 1239.)

References in Text

The Food, Drug, and Cosmetic Act, referred to in subsec. (b)(3)(A)(i), probably means the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (Sec. 301 et seq.) of this title. For complete classification of this Act to the Code, see section 301 of this title and Tables.

This subchapter, referred to in subsec. (b)(3)(D)(vi), (E), 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 subsecs. (b)(3)(D)(iv), (E) and (c)(2)(A), (B), was in the original ``title III'', meaning title III of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1285, as amended. 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.

The customs laws, referred to in subsec. (c)(2)(A), (B), are classified generally to Title 19, Customs Duties.

Amendments

2000--Subsec. (b)(3). Pub. L. 106-310 added subpars. (A), (D), and (E), redesignated former subpars. (A) and (B) as (B) and (C), respectively, and inserted ``or who engages in an export transaction'' after ``nonregulated person'' in introductory provisions of subpar. (B).

1996--Subsec. (a)(1). Pub. L. 104-237, Sec. 208, substituted ``for two years after the date of the transaction.'' for the dash after ``record of the transaction'' and struck out subpars. (A) and (B) which read as follows:

``(A) for 4 years after the date of the transaction, if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine; and

``(B) for 2 years after the date of the transaction, if the listed

chemical is a list II chemical.''

Subsec. (b)(3). Pub. L. 104-237, Sec. 402, added par. (3).

1993--Subsec. (a)(1). Pub. L. 103-200, Sec. 2(c)(1), substituted ``list I chemical'' for ``precursor chemical'' in subpar. (A) and ``a list II chemical'' for ``an essential chemical'' in subpar. (B).

Subsec. (b). Pub. L. 103-200, Sec. 10, designated existing provisions as par. (1), redesignated former pars. (1) to (4) as subpars. (A) to (D), respectively, in concluding provisions, substituted ``subparagraph (A)'' for ``paragraph (1)'' in two places, ``subparagraph (B)'' for ``paragraph (2)'', and ``subparagraph (C)'' for ``paragraph (3)'', and added par. (2).

Subsec. (c)(2)(D). Pub. L. 103-200, Sec. 2(c)(2), substituted ``chemical control laws'' for ``precursor chemical laws''.

1988--Pub. L. 100-690 amended section generally, substituting provisions relating to regulation of listed chemicals and certain machines for provisions relating to reporting by any person who distributes, sells, or imports any piperidine.

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 1988 Amendment

Amendment by Pub. L. 100-690 effective 120 days after Nov. 18, 1988, see section 6061 of Pub. L. 100-690, set out as a note under section 802 of this title.

Effective Date; Time To Submit Piperidine Report; Required Information

Section 203(a) of title II of Pub. L. 95-633 provided that:

``(1) Except as provided under paragraph (2), the amendments made by this title [enacting this section and amending sections 841 to 843 of this title] shall take effect on the date of the enactment of this Act [Nov. 10, 1978].

``(2) Any person required to submit a report under section 310(a)(1) of the Controlled Substances Act [subsec. (a)(1) of this section] respecting a distribution, sale, or importation of piperidine during the 90 days after the date of the enactment of this Act [Nov. 10, 1978] may submit such report any time up to 97 days after such date of enactment.

``(3) Until otherwise provided by the Attorney General by regulation, the information required to be reported by a person under section 310(a)(1) of the Controlled Substances Act (as added by section 202(a)(2) of this title) [subsec. (a)(1) of this section] with respect to the person's distribution, sale, or importation of piperidine shall--

``(A) be the information described in subparagraphs (A) and (B) of such section, and

``(B) except as provided in paragraph (2) of this subsection, be reported not later than seven days after the date of such distribution, sale, or importation.''

Repeals

Pub. L. 96-359, Sec. 8(b), Sept. 26, 1980, 94 Stat. 1194, repealed section 203(d) of Pub. L. 95-633, which had provided for the repeal of this section effective Jan. 1, 1981.

Regulations for Piperidine Reporting

Section 203(b) of Pub. L. 95-633 required the Attorney General to publish proposed interim regulations for piperidine reporting under section 830(a) of this title not later than 30 days after enactment, and final interim regulations not later than 75 days after enactment, such final interim regulations to be effective on and after the ninety-first day after enactment.

Report to President and Congress on Effectiveness of Title II of Pub. L. 95-633

Section 203(c) of Pub. L. 95-633 required the Attorney General to analyze and evaluate the impact and effectiveness of the amendments made by title II of Pub. L. 95-633, and report to the President and Congress not later than Mar. 1, 1980.