§ 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.A. § 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(49) of this title, except that this clause does not apply to sales of scheduled listed chemical products at retail.

(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(f)(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.

(d) Scheduled listed chemicals; restrictions on sales quantity; requirements regarding nonliquid forms

With respect to ephedrine base, pseudoephedrine base, or phenylpropanolamine base in a scheduled listed chemical product--

(1) the quantity of such base sold at retail in such a product by a regulated seller, or a distributor required to submit reports by subsection (b)(3) of this section may not, for any purchaser, exceed a daily amount of 3.6 grams, without regard to the number of transactions; and

(2) such a seller or distributor may not sell such a product in nonliquid form (including gel caps) at retail unless the product is packaged in blister packs, each blister containing not more than 2 dosage units, or where the use of blister packs is technically infeasible, the product is packaged in unit dose packets or pouches.

(e) Scheduled listed chemicals; behind-the-counter access; logbook requirement; training of sales personnel; privacy protections

(1) Requirements regarding retail transactions

(A) In general

Each regulated seller shall ensure that, subject to subparagraph (F), sales by such seller of a scheduled listed chemical product at retail are made in accordance with the following:

(i) In offering the product for sale, the seller places the product such that customers do not have direct access to the product before the sale is made (in this paragraph referred to as "behind-the-counter" placement). For purposes of this paragraph, a behind-the-counter placement of a product includes circumstances in which the product is stored in a locked cabinet that is located in an area of the facility involved to which customers do have direct access.

(ii) The seller delivers the product directly into the custody of the purchaser.

(iii) The seller maintains, in accordance with criteria issued by the Attorney General, a written or electronic list of such sales that identifies the products by name, the quantity sold, the names and addresses of purchasers, and the dates and times of the sales (which list is referred to in this subsection as the 'logbook'), except that such requirement does not apply to any purchase by an individual of a single sales package if that package contains not more than 60 milligrams of pseudoephedrine.

(iv) In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a product unless the sale is made in accordance with the following:

(I) The prospective purchaser--

(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006); and

(bb) signs the written logbook and enters in the logbook his or her name, address, and the date and time of the sale, or for transactions involving an electronic logbook, the purchaser provides a signature using one of the following means:

(AA) Signing a device presented by the seller that captures signatures in an electronic format. Such de-

vice shall display the notice described in clause (v). Any device used shall preserve each signature in a manner that clearly links that signature to the other electronically-captured logbook information relating to the prospective purchaser providing that signature.

(BB) Signing a bound paper book. Such bound paper book shall include, for such purchaser, either (aaa) a printed sticker affixed to the bound paper book at the time of sale which either displays the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale, or a unique identifier which can be linked to that electronic information, or (bbb) a unique identifier which can be linked to that information and which is written into the book by the seller at the time of sale. The purchaser shall sign adjacent to the printed sticker or written unique identifier related to that sale. Such bound paper book shall display the notice described in clause (v).

(CC) Signing a printed document that includes, for such purchaser, the name of each product sold, the quantity sold, the name and address of the purchaser, and the date and time of the sale. Such document shall be printed by the seller at the time of the sale. Such document shall contain a clearly identified signature line for a purchaser to sign. Such printed document shall display the notice described in clause (v). Each signed document shall be inserted into a binder or other secure means of document storage immediately after the purchaser signs the document.

(II) The seller enters in the logbook the name of the product and the quantity sold. Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(III) The logbook maintained by the seller includes the prospective purchaser's name, address, and the date and time of the sale, as follows:

(aa) If the purchaser enters the information, the seller must determine that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct.

(bb) If the seller enters the information, the prospective purchaser must verify that the information is correct.

(cc) Such information may be captured through electronic means, including through electronic data capture through bar code reader or similar technology.

(v) The written or electronic logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook, or supplying false information or identification that results in the entry of false statements or misrepresentations, may subject the purchasers to criminal penalties under section 1001 of title 18, United States Code, which notice specifies the maximum fine and term of imprisonment under such section.

(vi) Regardless of whether the logbook entry is written or electronic, the seller maintains each entry in the logbook for not fewer than 2 years after the date on which the entry is made.

(vii) In the case of individuals who are responsible for delivering such products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products, the seller has submitted to the Attorney General a self-certification that all such individuals have, in accordance with criteria under subparagraph (B)(ii), undergone training provided by the seller to ensure that the individuals understand the requirements that apply under this subsection and subsection (d) of this section.

(viii) The seller maintains a copy of such certification and records demonstrating that individuals referred to in clause (vii) have undergone the training.

(ix) If the seller is a mobile retail vendor:

(I) The seller complies with clause (i) by placing the product in a locked cabinet.

(II) The seller does not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(B) Additional provisions regarding certifications and training

(i) In general

A regulated seller may not sell any scheduled listed chemical product at retail unless the seller has submitted to the Attorney General the self-certification referred to in subparagraph (A)(vii). The certification is not effective for purposes of the preceding sentence unless, in addition to provisions regarding the training of individuals referred to in such subparagraph, the certification includes a statement that the seller understands each of the requirements that apply under this paragraph and under subsection (d) of this section and agrees to comply with the requirements.

(ii) Issuance of criteria; self-certification

The Attorney General shall by regulation establish criteria for certifications under this paragraph. The criteria shall--

(I) provide that the certifications are self-certifications provided through the program under clause (iii);

(II) provide that a separate certification is required for each place of business at which a regulated seller sells scheduled listed chemical products at retail; and

(III) include criteria for training under subparagraph (A)(vii).

(iii) Program for regulated sellers

The Attorney General shall establish a program regarding such certifications and training in accordance with the following:

(I) The program shall be carried out through an Internet site of the Department of Justice and such other means as the Attorney General determines to be appropriate.

(II) The program shall inform regulated sellers that section 1001 of Title 18 applies to such certifications.

(III) The program shall make available to such sellers an explanation of the criteria under clause (ii).

(IV) The program shall be designed to permit the submission of the certifications through such Internet site.

(V) The program shall be designed to automatically provide the explanation referred to in subclause (III), and an acknowledgement that the Department has received a certification, without requiring direct interactions of regulated sellers with staff of the Department (other than the provision of technical assistance, as appropriate).

(iv) Availability of certification to State and local officials

Promptly after receiving a certification under subparagraph (A)(vii), the Attorney General shall make available a copy of the certification to the appropriate State and local officials.

(C) Privacy protections

In order to protect the privacy of individuals who purchase scheduled listed chemical products, the Attorney General shall by regulation establish restrictions on disclosure of information in logbooks under subparagraph (A)(iii). Such regulations shall--

(i) provide for the disclosure of the information as appropriate to the Attorney General and to State and local law enforcement agencies; and

(ii) prohibit accessing, using, or sharing information in the logbooks for any purpose other than to ensure compliance with this subchapter or to facilitate a product recall to protect public health and safety.

(D) False statements or misrepresentations by purchasers

For purposes of section 1001 of Title 18 entering information in the logbook under subparagraph (A)(iii) shall be considered a matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States.

(E) Good faith protection

A regulated seller who in good faith releases information in a logbook under subparagraph (A)(iii) to Federal, State, or local law enforcement authorities is immune from civil liability for such release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(F) Inapplicability of requirements to certain sales

Subparagraph (A) does not apply to the sale at retail of a scheduled listed chemical product if a report on the sales transaction is required to be submitted to the Attorney General under subsection (b)(3) of this section.

(G) Certain measures regarding theft and diversion

A regulated seller may take reasonable measures to guard against employing individuals who may present a risk with respect to the theft and diversion of scheduled listed chemical products, which may include, notwithstanding State law, asking applicants for employment whether they have been convicted of any crime involving or related to such products or controlled substances.

(2) Mail-order reporting; verification of identity of purchaser; 30-day restriction on quantities for individual purchasers

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under subsection (b)(3) of this section to submit a report of the sales transaction to the Attorney General is subject to the following:

(A) The person shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General. The Attorney General shall by regulation establish such procedures.

(B) The person may not sell more than 7.5 grams of ephedrine base, pseudoephedrine base, or phenylpropanolamine base in such products per customer during a 30-day period.

(3) Exemptions for certain products

Upon the application of a manufacturer of a scheduled listed chemical product, the Attorney General may by regulation provide that the product is exempt from the provisions of subsection (d) of this section and paragraphs (1) and (2) of this subsection if the Attorney General determines that the product cannot be used in the illicit manufacture of methamphetamine.

CREDIT(S)

(Pub.L. 91-513, Title II, § 310, as added Pub.L. 95-633, Title II, § 202(a), Nov. 10, 1978, 92 Stat. 3774, and amended Pub.L. 100-690, Title VI, § 6052(a), Nov. 18, 1988, 102 Stat. 4312; Pub.L. 103-200, §§ 2(c), 10, Dec. 17, 1993, 107 Stat. 2336, 2341; Pub.L. 104-237, Title II, § 208, Title IV, § 402, Oct. 3, 1996, 110 Stat. 3104, 3111; Pub.L. 106-310, Div. B, Title XXXVI, § 3652, Oct. 17, 2000, 114 Stat. 1239; Pub.L. 109-177, Title VII, §§ 711(a)(2)(B), (b)(1), (c)(1), (2), (d), 716(b)(2), Mar. 9, 2006, 120 Stat. 257, 261, 267; Pub.L. 110-415, § 2, Oct. 14, 2008, 122 Stat. 4349.)

HISTORICAL AND STATUTORY NOTES

Revision Notes and Legislative Reports

1978 Acts. House Report No. 95-1193, see 1978 U.S. Code Cong. and Adm. News, p. 9496.

1988 Acts. For Related Reports, see 1988 U.S. Code Cong. and Adm. News, p. 5937.

House Report No. 103-379, see 1993 U.S. Code Cong. and Adm. News, p. 2983.

2006 Acts. House Conference Report No. 109-333, see 2006 U.S. Code Cong. and Adm. News, p. 184.

Statement by President, see 2006 U.S. Code Cong. and Adm. News, p. S7.

References in Text

The Food, Drug, and Cosmetic Act, referred to in subsec. (b)(3)(A)(i), is Act June 25, 1938, c. 675, 52 Stat. 1040, as amended, which is classified principally to chapter 9 of this title (21 U.S.C.A. § 301 et seq.). For complete classification of this Act to the Code, see Tables.

“This subchapter”, referred to in subsecs. (b)(3)(D)(vi) and (E) and (e)(1)(C)(ii), was in the original “this title” which is Title II of Pub.L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, known as the “Controlled Substances Act”. For complete classification, see Short Title note set out under 21 U.S.C.A. § 801 and Tables.

Subchapter II of this chapter, referred to in subsec. (b)(3)(D)(vi) and (E), was in the original “title III”, meaning Title III of Pub.L. 91-513, Oct. 27, 1970, 84 Stat. 1285. 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.

Amendments

2008 Amendments. Subsec. (e)(1)(A)(iv). Pub.L. 110-415, § 2, rewrote cl. (iv), which formerly read:

"(iv) In the case of a sale to which the requirement of clause (iii) applies, the seller does not sell such a product unless--

"(I) the prospective purchaser--

"(aa) presents an identification card that provides a photograph and is issued by a State or the Federal Government, or a document that, with respect to identification, is considered acceptable for purposes of sections 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B) of title 8, Code of Federal Regulations (as in effect on or after March 9, 2006; and

"(bb) signs the logbook and enters in the logbook his or her name, address, and the date and time of the sale; and

"(II) the seller--

"(aa) determines that the name entered in the logbook corresponds to the name provided on such identification and that the date and time entered are correct; and

"(bb) enters in the logbook the name of the product and the quantity sold.

Subsec. (e)(1)(A)(v). Pub.L. 110-415, § 2, rewrote cl. (v), which formerly read:

"(v) The logbook includes, in accordance with criteria of the Attorney General, a notice to purchasers that entering false statements or misrepresentations in the logbook may subject the purchasers to criminal penalties under section 1001 of Title 18, which notice specifies the maximum fine and term of imprisonment under such section.

Subsec. (e)(1)(A)(vi). Pub.L. 110-415, § 2, rewrote cl. (vi), which formerly read:

"(vi) The seller maintains each entry in the logbook for not fewer than two years after the date on which the entry is made."

2006 Amendments. Subsec. (b)(3)(D)(ii). Pub.L. 109-177, § 711(a)(2)(B), struck out "802(46) of this title" and inserted "802(49) of this title".

Pub.L. 109-177, § 711(c)(2), inserted before the period, “, except that this clause does not apply to sales of scheduled listed chemical products at retail”.

Subsec. (b)(3)(D)(v). Pub.L. 109-177, § 716(b)(2), struck out “section 971(e)(2)” and inserted “section 971(f)(2)”.

Subsec. (d). Pub.L. 109-177, § 711(b)(1), added subsec. (d).

Subsec. (e)(1). Pub.L. 109-177, § 711(b)(1), added subsec. (e)(1).

Subsec. (e)(2). Pub.L. 109-177, § 711(c)(1), added subsec. (e)(2).

Subsec. (e)(3). Pub.L. 109-177, § 711(d), added subsec. (e)(3).

2000 Amendments. Subsec. (b)(3)(A). Pub.L. 106-310, § 3652(1), (2), added subpar. (A) and redesignated former subpar. (A) as (B). Former subpar. (B) redesignated (C).

Subsec. (b)(3)(B). Pub.L. 106-310, § 3652(1), (3), redesignated former subpar. (A) as (B) and, as so redesignated, inserted “or who engages in an export transaction” following “nonregulated person”. Former subpar. (B) redesignated (C).

Subsec. (b)(3)(C). Pub.L. 106-310, § 3652(1), redesignated former subpar. (B) as (C). Former subpar. (A) redesignated (B).

Subsec. (b)(3)(D), (E). Pub.L. 106-310, § 3652(4), added subpars. (D) and (E).

1996 Amendments. Subsec. (a)(1). Pub.L. 104-237, § 208, substituted “for two years after the date of the transaction” for “--”. Former subpars. (A) and (B), which provided for a four-year record-keeping date if the listed chemical is a list I chemical or if the transaction involves a tableting machine or an encapsulating machine, and a two-year record-keeping date if the listed chemical is a list II chemical, respectively, were struck out.

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

1993 Amendments. Subsec. (a)(1)(A). Pub.L. 103-200, § 2(c)(1)(A), substituted “list I chemical” for “precursor chemical”.

Subsec. (a)(1)(B). Pub.L. 103-200, § 2(c)(1)(B), substituted “a list II chemical” for “an essential chemical”.

Subsec. (b). Pub.L. 103-200, § 10, designated existing provisions of subsec. (b) as subsec. (b)(1); redesignated for-

mer pars. (1), (2), (3), and (4) as subpars. (A), (B), (C), and (D), respectively; substituted “subparagraph (A)” for “paragraph (1)” wherever appearing; substituted “subparagraph (B)” for “paragraph (2)”; substituted “subparagraph (C)” for “paragraph (3)”; and added par. (2).

Subsec. (c)(2)(D). Pub.L. 103-200, § 2(c)(2), substituted “chemical control” for “precursor chemical”.

1988 Amendments. Heading. Pub.L. 100-690 substituted “Regulation of listed chemicals and certain machines” for “Piperidine reporting”.

Subsecs. (a), (b). Pub.L. 100-690 added subsecs. (a) and (b), incorporating in part provisions of former subsec. (a), which read:

“(1) Except as provided under paragraph (3), any person who distributes, sells, or imports any piperidine shall report to the Attorney General such information, in such form and manner, and within such time period or periods (of not less than seven days), concerning the distribution, sale, or importation as the Attorney General may require by regulation, and the person shall preserve a copy of each such report for 2 years. The Attorney General may include in the information required to be reported the following:

“(A) The quantity, form, and manner in which, and date on which, the piperidine was distributed, sold, or imported.

“(B)(i) In the case of the distribution or sale of piperidine to an individual, the name, address, and age of the individual and the type of identification presented to confirm the identity of the individual.

“(ii) In the case of the distribution or sale of piperidine to an entity other than an individual, the name and address of the entity and the name, address, and title of the individual ordering or receiving the piperidine and the type of identification presented to confirm the identity of the individual and of the entity.

“(2) Except as provided under paragraph (3), no person may distribute or sell piperidine unless the recipient or purchaser presents to the distributor or seller identification of such type, to confirm the identity of the recipient or purchaser (and any entity which the recipient or purchaser represents), as the Attorney General establishes by regulation.

“(3) Under such conditions and to such extent as the Attorney General establishes, paragraphs (1) and (2) shall not apply to--

“(A) the distribution of piperidine between agents or employees within a single facility (as defined by the Attorney General), if such agents or employees are acting in the lawful and usual course of their business or employment;

"(B) the delivery of piperidine to or by a common or contract carrier for carriage in the lawful and usual course of its business, or to or by a warehouseman for storage in the lawful and usual course of its business; but where such carriage or storage is in connection with the distribution, sale, or importation of the piperidine to a third person, this subparagraph shall not relieve the distributor, seller, or importer from compliance with paragraph (1) or (2); or

"(C) any distribution, sale, or importation of piperidine with respect to which the Attorney General determines that the report required by paragraph (1) or the presentation of identification required by paragraph (2) is not necessary for the enforcement of this subchapter."; and struck out subsec. (b) relating to confidential information, covered in subsec. (c) of this section."

Subsec. (c). Pub.L. 100-690 added subsec. (c), incorporating in part provisions of former subsec. (b), which read "Any information which is reported to or otherwise obtained by the Department of Justice under this section and which is exempt from disclosure pursuant to subsection (a) of section 552 of Title 5 by reason of subsection (b)(4) thereof shall be considered confidential and shall not be disclosed, except that such information may be disclosed to officers or employees of the United States concerned with carrying out this subchapter or subchapter II of this chapter or when relevant in any proceeding for the enforcement of this subchapter or subchapter II of this chapter."; and struck out former subsec. (c)(1)-(3), defining terms "import", "phencyclidine", and "piperidine".

Effective and Applicability Provisions

2006 Acts. Pub.L. 109-177, Title VII, § 711(b)(2), Mar. 9, 2006, 120 Stat. 261, provided that:

"With respect to subsections (d) and (e)(1) of section 310 of the Controlled Substances Act, as added by paragraph (1) of this subsection [Pub.L. 109-177, Title VII, § 711(b)(1), Mar. 9, 2006, 120 Stat. 257, amending Pub.L. 91-513, Title II, § 310, as added by Pub.L. 95-633, Title II, § 202(a), Nov. 10, 1978, 92 Stat. 3774, which is classified to this section, by adding subsections (d) and (e)(1)]:

"(A) Such subsection (d) applies on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [March 9, 2006].

"(B) Such subsection (e)(1) applies on and after September 30, 2006."

Pub.L. 109-177, Title VII, § 711(c)(3), Mar. 9, 2006, 120 Stat. 261, provided that: "The amendments made by paragraphs (1) and (2) [Pub.L. 109-177, Title VII, § 711(c)(1) and (2), Mar. 9, 2006, 120 Stat. 261, amending subsections (b)(3)(D)(ii) and (e)(2) of this section]apply on and after the expiration of the 30-day period beginning on the date of the enactment of this Act [March 9, 2006]."

1993 Acts. Amendment to this section by Pub.L. 103-200, to take effect on the date that is 120 days after the date of enactment of Pub.L. 103-200, which was approved Dec. 17, 1993, see section 11 of Pub.L. 103-200, set out as a note under section 802 of this title.

1988 Acts. Amendment by section 6052 of 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 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 [subsec. (a)(1) of this section] (as added by section 202(a)(2) of this title) 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."

Effective Date of Repeal

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

Combat Methamphetamine Epidemic Act of 2005--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 though 717 and section 721 of the Combat Methamphetamine Epidemic Act of 2005, the Attorney General shall consult with the United States Trade Representative to insure compliance with all applicable international treaties and obligations of the United States, see Pub.L. 109-177, § 718, set out as a note under 21 U.S.C.A. § 826.

Regulations for Piperidine Reporting

Section 203(b) of Pub.L. 95-633 provided that: "The Attorney General shall--

“(1) first publish proposed interim regulations to carry out the requirements of section 310(a) of the Controlled Substances Act [subsec. (a) of this section] (as added by section 202(a)(2) of this title) not later than 30 days after the date of the enactment of this Act [Nov. 10, 1978], and

“(2) first promulgate final interim regulations to carry out such requirements not later than 75 days after the date of the enactment of this Act [Nov. 10, 1978], such final interim regulations to be effective with respect to distributions, sales, and importations of piperidine on and after the ninety-first day after the date of the enactment of this Act [Nov. 10, 1978].”

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, after consultation with the Secretary of Health, Education, and Welfare [now Secretary of Health and Human Services], to analyze and evaluate the impact and effectiveness of the amendments made by Title II of Pub.L. 95-633 [enacting this section and amending sections 841 to 843 of this title], including the impact on the illicit manufacture and use of phencyclidine and the impact of the requirements imposed by such amendments on legitimate distributions and uses of piperidine, and, not later than Mar. 1, 1980, to report to the President and the Congress on such analysis and evaluation and to include in such report such recommendations as he deemed appropriate.

CODE OF FEDERAL REGULATIONS

Confidential patient records, drug abuse, see 42 CFR § 2.1 et seq.

Controlled drugs, warnings, see 21 CFR § 290.5 et seq.

Identification requirements, see 21 CFR § 1310.01 et seq.

LIBRARY REFERENCES

American Digest System

Drugs and Narcotics 41.
Key Number System Topic No. 138.

RESEARCH REFERENCES

Encyclopedias

Am. Jur. 2d Drugs and Controlled Substances § 27, Federal Statutes, Generally.

Am. Jur. 2d Drugs and Controlled Substances § 32, Finality of Agency Findings, Conclusions, and Decisions; Review.

Am. Jur. 2d Drugs and Controlled Substances § 34, Controlled-Substance Schedules, Generally.

Am. Jur. 2d Drugs and Controlled Substances § 40, Effect of International Treaties, Conventions, or Protocols.

Am. Jur. 2d Drugs and Controlled Substances § 64, Who Must Register--Practitioners.

Am. Jur. 2d Drugs and Controlled Substances § 68, Records and Reports.

Am. Jur. 2d Drugs and Controlled Substances § 141, Manufacture, Distribution, or Delivery of Substance.

Am. Jur. 2d Drugs and Controlled Substances § 162, Generally; Manufacture, Distribution, or Possession of Substances.

Am. Jur. 2d Drugs and Controlled Substances § 165, Violation of Labeling or Sealing Requirements, Generally.

Am. Jur. 2d Drugs and Controlled Substances § 166, Fraud and Related Conduct in Manufacture, Obtaining, or Distribution of Substances.

Am. Jur. 2d Drugs and Controlled Substances § 169, Violation of Recordkeeping or Inspection Requirements; Disclosure of Confidential Information.

Am. Jur. 2d Freedom of Information Acts § 615, Particular Types of Remedies and Relief.

NOTES OF DECISIONS

1. Due process

Obligation of pharmaceutical manufacturer and its officers under Controlled Substances Act (CSA), to report "extraordinary quantity" of pseudoephedrine tablets purchased by any customer, was not unconstitutionally vague under due process clause of Fifth Amendment, where federal officials specifically instructed manufacturer that it should

consider usual orders placed by its established customers to determine whether particular order was for "extraordinary quantity," and common sense meaning of phrase "extraordinary quantity" sufficed to alert any manufacturer that it was required to report pseudoephedrine quantities that went beyond what was usual, regular, common, or customary. Advance Pharmaceutical, Inc. v. U.S., C.A.2 (N.Y.) 2004, 391 F.3d 377. Constitutional Law 4516; Controlled Substances 6

Chemical distributor was likely to prevail on its claim that government officials were not authorized to prohibit suppliers from selling certain chemicals to distributor which could be used to manufacture illegal drugs, for purpose of obtaining preliminary injunctive relief; statute did not appear to authorize across the board relief on domestic transactions involving certain individuals and, if it did, deprived such individuals of due process by failing to provide for notice and hearing. Chemicals for Research and Industry v. Thornburgh, N.D.Cal.1991, 762 F.Supp. 1394. Injunction 138.46

2. Extraordinary quantity

Shipments of less than one million pseudoephedrine tablets, as listed chemical, to customer was "extraordinary," and, consequently, pharmaceutical manufacturer and its officers were civilly liable under Controlled Substances Act (CSA) for failing to report those shipments to Drug Enforcement Administration (DEA), since evidence of previous day's shipment would have indicated to manufacturer that total quantity shipped within that brief time was extraordinary, or manufacturer persisted in failing to report shipments to that customer even after being advised by DEA and California Bureau of Narcotic Enforcement (CBNE) that tablets sold to that distributor had been linked to illegal manufacture of methamphetamine. Advance Pharmaceutical, Inc. v. U.S., C.A.2 (N.Y.) 2004, 391 F.3d 377. Controlled Substances 21

3. Identity of purchaser

Company that sold household products to local retailers for consumer sale and its owner violated Comprehensive Drug Abuse Prevention Control Act and related regulations when, for eight transactions involving sales of cold medicine containing regulated chemical, buyers did not present any documents verifying their identities or registration statuses at the time of their orders. U.S. v. Global Distributors, Inc., C.A.7 (Ill.) 2007, 498 F.3d 613. Controlled Substances 21

21 U.S.C.A. § 830, 21 USCA § 830

Current through P.L. 111-112 (excluding P.L. 111-84) approved 11-30-09

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