

Note that these inflation adjustments are based on the Gross Domestic Product (GDP) Implicit Price Deflator, rather than the Gross National Product (GNP) Implicit Price Deflator, which is not yet available for 1996. The Commerce Department advises that in recent years the annual change has been virtually the same for both indices. Further adjustments will be made, if necessary.

List of Subjects in 18 CFR Part 157

Natural gas.
Kevin P. Madden,
Director, Office of Pipeline Regulation.

Accordingly, 18 CFR Part 157 is amended as follows:

PART 157—[AMENDED]

1. The authority citation for part 157 continues to read as follows:

Authority: 15 U.S.C. 717-717w, 3301-3432; 42 U.S.C. 7101-7352.

§ 157.208 [Amended]

2. Table I in § 157.208(d) is revised to read as follows:

§ 157.208 Construction, acquisition, operation, and miscellaneous rearrangement of facilities.

* * * * *

(d) * * *

TABLE I

Year	Limit	
	Auto. proj. cost limit (col. 1)	Prior notice proj. cost limit (col. 2)
1982	\$4,200,000	\$12,000,000
1983	4,500,000	12,800,000
1984	4,700,000	13,300,000
1985	4,900,000	13,800,000
1986	5,100,000	14,300,000
1987	5,200,000	14,700,000
1988	5,400,000	15,100,000
1989	5,600,000	15,600,000
1990	5,800,000	16,000,000
1991	6,000,000	16,700,000
1992	6,200,000	17,300,000
1993	6,400,000	17,700,000
1994	6,600,000	18,100,000
1995	6,700,000	18,400,000
1996	6,900,000	18,800,000
1997	7,000,000	19,200,000

* * * * *

§ 157.215 [Amended]

3. Table II in § 157.215(a) is revised to read as follows:

§ 157.215 Underground storage testing and development.

(a) * * *

TABLE II

Year	Limit
1982	\$2,700,000
1983	2,900,000
1984	3,000,000
1985	3,100,000
1986	3,200,000
1987	3,300,000
1988	3,400,000
1989	3,500,000
1990	3,600,000
1991	3,800,000
1992	3,900,000
1993	4,000,000
1994	4,100,000
1995	4,200,000
1996	4,300,000
1997	4,400,000

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309, 1310, and 1313

[DEA Number 154I]

RIN 1117-AA42

Comprehensive Methamphetamine Control Act of 1996; Possession of List I Chemicals, Definitions, Record Retention, and Temporary Exemption From Chemical Registration for Distributors of Combination Ephedrine Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim rule with request for comments.

SUMMARY: DEA is amending its regulations to incorporate certain amendments of the Controlled Substances Act (CSA) made by the Comprehensive Methamphetamine Control Act of 1996 (MCA) and to provide temporary exemption from registration for persons who distribute combination ephedrine drug products. The MCA amends the CSA with respect to: possession of listed chemicals following suspension or revocation of registration; the record retention requirements for List I chemical transactions; certain definitions; and establishes the requirement that, effective October 3, 1996, persons that distribute combination ephedrine products shall be subject to the chemical registration requirement. To avoid interruption in the legitimate distribution of combination ephedrine products, DEA is amending its

regulations to provide certain temporary exemptions from the registration requirement pending promulgation of final regulations.

DATES: Effective February 10, 1997. Written comments or objections must be submitted on or before April 11, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION: The Comprehensive Methamphetamine Control Act of 1996 was enacted on October 3, 1996. Among its provisions, the MCA contained revisions of the Controlled Substances Act (CSA) with respect to possession of listed chemicals following revocation or suspension of registration, the record retention requirements for transactions involving List I chemicals and tableting or encapsulating machines, and definitions, of "regulated transaction", "retail distributor", and "combination ephedrine product". To accommodate the amendments made by the MCA, DEA is making the following changes to Title 21, Code of Federal Regulations (CFR):

21 CFR 1309.43 Suspension or Revocation of Registration

The MCA amends Section 404 of the CSA (21 U.S.C. 844) to make it unlawful for any person to knowingly or intentionally possess any list I chemical obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, if that registration or exemption has been revoked or suspended. The revised language also makes it illegal to possess list I chemicals obtained under the authority of a registration or an exemption granted by regulation by the Administrator, if the registration has expired or if the registrant has ceased to do business as originally intended under that registration.

To reflect the amendments in the law, DEA is revising 21 CFR 1309.43, to include seizure and forfeiture instructions. Persons whose registrations or exemptions have been revoked or suspended shall be required, upon service of the notice of revocation or suspension, to surrender all List I

chemicals in their possession obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, to the nearest office of the Administration or authorized agent of the Administration, or place such List I chemicals under seal as described in 21 U.S.C. 824(f). When the suspension or revocation is limited to certain chemicals, the registrant shall surrender those chemicals affected by the revocation or suspension as indicated above.

21 CFR 1309.02, 1310.01 & 1313.02 Definitions

The definition of "retail distributor" found in § 1309.02(f) has been amended by the MCA. As defined by the MCA, the term refers to persons, such as grocery stores, general merchandise stores, drug stores, etc., that engage in sales of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products almost exclusively to individuals for personal use in face-to-face transactions. The new definition will apply to all retail distributors of regulated drug products, including single entity ephedrine products.

The MCA also amends the definition of "regulated transaction" to make all ephedrine products and certain drug products containing pseudoephedrine and phenylpropanolamine subject to regulation. However, because the provisions relating to pseudoephedrine and phenylpropanolamine products will not become effective until October 3, 1997, the definition of "regulated transaction", as found in 21 CFR 1310.01(f) and 1313.02(d), is being amended only with respect to ephedrine products at this time. The MCA also defines "combination ephedrine product"; that definition, together with the appropriate guidelines clarifying the specific criteria established by the definition, has been added to §§ 1309.02 and 1310.01.

As a result of the amendment to the definition of "regulated transaction", persons who distribute, import, or export combination ephedrine products are now subject to the chemical registration, recordkeeping, and reporting requirements. As noted later in this document, DEA is establishing certain temporary exemptions from the registration requirement pending promulgation of regulations, subject to notice and comment, relating to the control of combination ephedrine products.

21 CFR 1310.02 Substances Covered and 21 CFR 1310.04 Maintenance of Records

The MCA amends Section 802(34) of the CSA to correct the spelling of "Isosafrole" and "hydriodic acid" and Section 830(a) to modify the record retention period from the current 4 years to 2 years for all transactions involving a listed chemical or a tableting or encapsulating machine. The corresponding amendments are being made in the regulations. With respect to the change in the record retention period, the new language of the law does not distinguish between records created before and after the change in the retention requirement. Thus, effective October 3, 1996, a regulated person's records must only contain records of those regulated transactions that occurred within the past two years; records of transactions that are more than two years old are no longer required.

Temporary Exemptions From Registration Pending Promulgation, With Notice and Comment, of Regulations

As noted earlier, combination ephedrine products became subject to the CSA's chemical registration, recordkeeping, and reporting provisions effective October 3, 1996. Under this new requirement, any person who distributes, imports, or exports combination ephedrine products must first obtain a DEA registration. Because implementation of this provision will require amendment to DEA's regulations, DEA is establishing temporary exemptions from the registration requirement for persons handling combination ephedrine products, to allow for continuation of legitimate commerce in the products. In addition, the existing exemptions from chemical registration for persons registered with DEA to handle controlled substances, which is contained in 21 CFR 1309.25 and for distributors of prescription drug products, which is contained in 21 CFR 1309.28, are continued for combination ephedrine products.

The first new exemption applies to retail distributors of combination ephedrine products. A single transaction limit of 24 grams has been established by the MCA for combination ephedrine products in retail distributions. Consistent with previous proposals regarding the regulation of retail distributions of drug products that contain List I chemicals, DEA is temporarily exempting retail distributors from the registration

requirement. This interim rule is subject to public comment. Under this exemption, retail distributors will not be required to obtain a registration if they engage exclusively in distributions of combination ephedrine products below the 24 gram limit in a single transaction for legitimate medical use either directly to walk-in customers or in face-to-face transactions by direct sales. This exemption is set out in the new section 21 CFR 1309.29. Retail distributors that operate under this exemption are reminded that they will be subject to civil penalties for violations of the 24 gram single transaction limit, as set out in Section 401(f)(2) of the MCA.

The second exemption applies to those persons (other than retail distributors, as described above, or persons subject to the existing exemptions regarding CSA registrants and prescription drug products) who are required to obtain a registration. Any such person who submits an application for registration for activities involving combination ephedrine products on or before May 12, 1997 will be exempt from the registration requirement for their lawful activities with combination ephedrine products until the Administration has taken final action with respect to that application. This exemption is set out in 21 CFR 1310.09.

DEA recognizes that, unlike the second exemption, which provides a general benefit to all affected persons, the first exemption is limited in its benefit. Therefore, while the regulatory changes in this interim rule take effect upon publication, the notice is open for public comment or objection until May 12, 1997. Further, the exemptions are temporary and may be subject to change, based on the comments or objections received.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this interim rulemaking will not have a significant economic impact upon a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* This interim rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration pending promulgation, through notice and comment, of the regulations necessary to implement the provisions of the MCA pertaining to combination ephedrine products. Further, since this is a temporary action which provides affected persons with a means to comply with the law pending promulgation of regulations implementing the MCA, this action is

not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866. Consideration of the significance and impact of the new requirements of the MCA will be addressed as part of a future proposed rulemaking by DEA proposing regulations to implement the MCA.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this interim rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

21 CFR Part 1313

Drug traffic control, Exports, Imports, list I and List II chemicals, Transshipment and in-transit shipments.

For the reasons set out above, 21 CFR Parts 1309, 1310, and 1313 are to be amended as follows:

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS AND EXPORTERS OF LIST I CHEMICALS

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.29 is added to read as follows:

§ 1309.29 Exemption of retail distributors of combination ephedrine drug products.

The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are restricted to the distribution of below-threshold quantities of a combination ephedrine drug product in a single transaction to an individual for legitimate medical use. The threshold for a distribution of a combination ephedrine drug product in a single transaction to an individual for legitimate medical use is 24 grams of ephedrine base.

2. Section 1309.43 is amended by revising paragraph (d) and adding a new paragraph (e) to read as follows:

§ 1309.43 Suspension or revocation of registration.

* * * * *

(d) Upon service of the order of the Administrator suspending or revoking registration, the registrant shall immediately deliver his or her Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revoking or suspending registration, the registrant shall, as instructed by the Administrator:

(1) Deliver all List I chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, to the nearest office of the Administration or to authorized agents of the Administration; or

(2) Place all such List I chemicals in his or her possession under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

(e) In the event that revocation or suspension is limited to a particular chemical or chemicals, the registrant shall be given a new Certificate of Registration for all substances not affected by such revocation or suspension; no fee shall be required for the new Certificate of Registration. The registrant shall deliver the old Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of the Administrator revoking or suspending registration with respect to a particular chemical or chemicals, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

3. Section 1309.44 is amended by revising paragraph (b) to read as follows:

§ 1309.44 Suspension of registration pending final order.

* * * * *

(b) Upon service of the order of immediate suspension, the registrant shall promptly return his Certificate of Registration to the nearest office of the Administration. Also, upon service of the order of immediate suspension, the registrant shall, as instructed by the Administrator:

(1) Deliver to the nearest office of the Administration or to authorized agents of the Administration all of the particular chemical or chemicals in his or her possession that were obtained under the authority of a registration or an exemption from registration granted by the Administrator by regulation, which are affected by the revocation or suspension; or

(2) Place all of such chemicals under seal as described in section 304(f) of the Act (21 U.S.C. 824(f)).

* * * * *

4. Section 1309.62 is to be amended by revising the existing text and redesignating it as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 1309.62 Termination of registration.

(a) The registration of any person shall terminate if and when such person dies, ceases legal existence, or discontinues business or professional practice. Any registrant who ceases legal existence or discontinues business or professional practice shall promptly notify the Special Agent in Charge of the Administration in the area in which the person is located of such fact and seek authority and instructions to dispose of any List I chemicals obtained under the authority of that registration.

(b) The Special Agent in Charge shall authorize and instruct the person to dispose of the List I chemical in one of the following manners:

(1) By transfer to person registered under the Act and authorized to possess the substances;

(2) By delivery to an agent of the Administration or to the nearest office of the Administration;

(3) By such other means as the Special Agent in Charge may determine to assure that the substance does not become available to unauthorized persons.

PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.01 is amended by revising paragraphs (f)(1)(iv)(A) and (B) redesignating paragraphs (g) through (l) as paragraphs (h) through (m), redesignating paragraph (m) as paragraph (o), and adding new paragraphs (g) and (n) to read as follows:

§ 1310.01 Definitions.

* * * * *

(f) * * *

(1) * * *

(iv) * * *

(A) (1) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers; or

(2) The Administrator has determined pursuant to the criteria in 1310.10 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(B) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical.

* * * * *

(g) The term combination ephedrine product means a drug product containing ephedrine or its salts, optical isomers, or salts of optical isomers and therapeutically significant quantities of another active medicinal ingredient. The term "therapeutically significant quantities" shall apply if the product formulation (i.e., the qualitative and quantitative composition of active ingredients within the product) is listed in American Pharmaceutical Association (APHA) Handbook of NonPrescription Drugs; Drug Facts and Comparisons (published by Wolters Kluwer Company); or USP DI (published by authority of the United States Pharmacopeial Convention, Inc.); or the product is listed in § 1310.15 as an exempt drug product. For drug products having formulations not found in the above compendiums, the Administrator shall determine, pursuant to a written request as specified in § 1310.14 whether the active medicinal ingredients are present in quantities considered therapeutically significant for purposes of this paragraph.

* * * * *

(n) The term retail distributor means a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing pseudoephedrine, phenylpropanolamine, or ephedrine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. For the purposes of this paragraph, sale for personal use means the distribution of below-threshold quantities in a single transaction to an individual for legitimate medical use. Also for the purposes of this paragraph, a grocery store is an entity within Standard Industrial Classification (SIC) code 5411, a general merchandise store is an entity within SIC codes 5300 through

5399 and 5499, and a drug store is an entity within SIC code 5912.

* * * * *

3. Section 1310.02 is amended by revising paragraphs (a)(16) and (a)(21) to read as follows:

§ 1310.02 Substances covered.

* * * * *

(a) * * *

(16) Isosafrole 8704

* * * * *

(21) Hydriodic Acid 6695

* * * * *

4. Section 1310.04 is amended by revising paragraph (a) to read as follows:

§ 1310.04 Maintenance of records.

(a) Every record required to be kept subject to § 1310.03 for a List I chemical, a tableting machine, or an encapsulating machine shall be kept by the regulated person for two years after the date of the transaction.

* * * * *

5. Section 1310.09 is revised to read as follows:

§ 1310.09 Temporary exemption from registration.

Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a combination ephedrine product is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before May 12, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

PART 1313—IMPORTATION AND EXPORTATION OF PRECURSORS AND ESSENTIAL CHEMICALS

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.02 is amended by revising paragraphs (d)(1)(iv)(A) and (B), to read as follows:

§ 1313.02 Definitions.

* * * * *

(d) * * *

(1) * * *

(iv) * * *

(A)(1) the drug contains ephedrine or its salts, optical isomers, or salts of optical isomers; or

(2) The Administrator has determined pursuant to the criteria in 1310.10 that the drug or group of drugs is being diverted to obtain the listed chemical for use in the illicit production of a controlled substance; and

(B) The quantity of ephedrine or other listed chemical contained in the drug included in the transaction or multiple transactions equals or exceeds the threshold established for that chemical.

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Dated: January 28, 1997.

Gene R. Haislip,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Parts 404 and 407

RIN 2135-AA08

Seaway Regulations and Rules: Great Lakes Pilotage Rates

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Saint Lawrence Seaway Development Corporation (SLSDC) amends the Seaway Regulations and Rules by increasing Great Lakes Pilotage Rates by: 8% in District 1 (9% in Area 1; 6% in Area 2); 19% in District 2 (0% in Area 4; 31% in Area 5); 6% in District 3 (7% in Area 6; 6% in Area 7; 4% in Area 8); and 11% for mutual rates.

The pilotage rate adjustments contained in this final rule are different from the rates proposed by the SLSDC in the Notice of Proposed Rulemaking published in the Federal Register (61 FR 50258) on September 25, 1996, (the NPRM), because adjustments have been made based on comments received in response to the NPRM. These adjustments are discussed in the section of this rule entitled "Discussion of Comments and Changes."

The increase in Great Lakes pilotage rates is necessary because, after review, the SLSDC has determined that, in accordance with 33 CFR 407.1(b), pilot compensation is not meeting pilot compensation targets established in 33 CFR Part 407, Appendix A, Step 2.

EFFECTIVE DATE: This rule becomes effective on March 1, 1997.

FOR FURTHER INFORMATION CONTACT: Scott A. Poyer, Chief Economist, Saint