

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300 and 1313

[Docket No. DEA-292F]

RIN 1117-AB06

**Implementation of the Combat Methamphetamine Epidemic Act of 2005; Notice of
Transfers Following Importation or Exportation**

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This regulation implements section 716 of the Combat Methamphetamine Epidemic Act of 2005 (CMEA) (21 U.S.C. § 971 as amended), which was enacted on March 9, 2006. DEA is amending its regulations to require additional reporting for import, export, and international transactions involving all List I and List II chemicals. This rule implements § 716 of the CMEA which extends current reporting requirements for importations, exportations, and international transactions involving List I and List II chemicals.

EFFECTIVE DATE: [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington DC 20537 at (202) 307-7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and Controlled Substances Import and Export Act (21 U.S.C. § 801 et seq.), as amended. DEA publishes the implementing regulations for this statute in Title 21 of the Code of Federal Regulations (CFR), Parts 1300 to end. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture and distribution of chemicals that may be used to manufacture controlled substances. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and

Reauthorization Act of 2005 (Pub. L. 109-177). DEA is promulgating this rule as a final rule rather than a proposed rule because the changes being made merely codify statutory provisions. The statute is self-implementing; the changes discussed in this rule became effective on March 9, 2006. An agency may find good cause to exempt a rule from certain provisions of the Administrative Procedure Act (APA) (5 U.S.C. § 553), including Notice of Proposed Rulemaking and the opportunity for public comment, if it is determined to be unnecessary, impracticable, or contrary to the public interest. The requirements of the Combat Methamphetamine Epidemic Act of 2005 included in this rulemaking were set out in such detail as to be self-implementing. Therefore the changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. DEA has no authority to revise the changes and is simply implementing, and making its regulations conform to, the statute.

Combat Methamphetamine Epidemic Act of 2005

The portion of the CMEA being implemented in this rulemaking addresses the importation, exportation, and international transactions of all List I and List II chemicals. Section 716 of the CMEA (21 U.S.C. § 971 as amended) closes a loophole in the current regulatory system for imports, exports, and international transactions of listed chemicals used in the illicit manufacture of controlled substances. Prior to enactment of the CMEA, a company that wanted to import or export any List I or List II chemical was required to either: (1) notify the Department of Justice 15 days in advance of the import or export; or (2) be a company that previously imported or exported a listed chemical and that was proposing to import from or export the chemicals to a customer with whom the company had previously dealt. (See 21 U.S.C. § 971(a), (b))

A problem can arise, however, when the sale that the importer or exporter originally planned falls through. When this happens, the importer or exporter must quickly find a new buyer for the chemicals on what is called the "spot market" -- a wholesale market. Sellers are often under pressure to find a buyer in a short amount of time, meaning that they may be tempted to entertain bids from companies without a strong record of preventing diversion. More importantly, DEA is not made aware of, and has no opportunity to review, such transactions in advance in order to suspend them if there is a danger of diversion to the clandestine manufacture of a controlled substance.

Section 716 of the CMEA extends the current reporting requirements -- as well as the current exemption for regular importers and regular customers -- to post-import and post-export transactions of List I and List II chemicals. Importers, exporters, brokers, and traders are now required to notify DEA, prior to consummating a transaction, of certain information regarding their downstream customers. If the person to whom the chemical is being transferred is not a regular customer, the importer, exporter, broker, or trader must notify DEA no later than 15 days prior to consummating the transaction; upon receipt, DEA will have 15 days to review the notification. Specifically, the United States importer or exporter must provide the name and address of each person to whom the listed chemicals will be transferred, and the name and quantity of the listed chemicals to be transferred, including package information. This person is referred to as the "transferee" of the United States importer or exporter. The spot market reporting requirements also apply, to a limited extent, to United States brokers and traders that arrange international transactions (i.e., transactions between customers in two foreign countries).

For a United States exporter, the transferee is the foreign importer. Thus, this aspect of the new requirement does not represent a change for United States exporters, who have previously notified DEA of information on their purchasers. For a United States broker or trader, the transferee is the foreign customer purchasing the listed chemicals. Again, this requirement is not a change for brokers and traders, who have previously notified DEA of information on their purchasers.

The requirement is, however, a change for United States importers. For a United States importer, the "transferee" is the person to whom the importer transfers the listed chemicals -- the downstream customer. Until the CMEA, importers were required to provide information regarding their suppliers, but not regarding the parties purchasing the chemicals in the United States. Under the CMEA, importers will have to list both the foreign supplier and each U.S. customer for the imported chemical.

The provision of customer information by the importer provides DEA with an opportunity to evaluate the transaction. DEA will have 15 days from the time the customer information is submitted to review the transaction and determine whether it may be diverted to the clandestine manufacture of a controlled substance. If DEA determines that the transaction does not pose an unacceptable risk of diversion, DEA will take no action. The importer will thus be granted regular importer status for transactions involving the specific chemical to be imported to the specific customer. The transferee -- the downstream customer -- will be granted regular customer status for imports of the specified chemical by the specified importer. DEA must review each import transaction based not only on the chemical to be imported, but also on the transferee to whom the chemical will be transferred.

If, after submission of the initial DEA Form 486, Import/Export Declaration, the importer, exporter, broker, or trader will not be transferring the listed chemical to the person initially named on the DEA Form 486, or if the importer or exporter will be transferring a greater quantity than originally indicated on the DEA Form 486, then the importer, exporter, broker, or trader must file an amended DEA Form 486 reporting the change. This is a new requirement for both United States importers and exporters, as well as brokers and traders. This amendment must provide the name of the new prospective customer and/or the greater quantity of the listed chemical to be transferred. The requirement to notify DEA of a change in the transferee or an increase in the quantity of the chemical to be transferred applies to amended DEA Forms 486 in the same manner that it applies to original submissions.

Thus, if an importer, exporter, broker, or trader is required to file an initial advance notice with DEA 15 days before the shipment or arrival of chemicals, and the originally planned sale falls through, the importer, exporter, broker, or trader is required to file a second advance notice with DEA, identifying the new proposed purchaser. DEA will again have 15 days to review the new transaction and determine whether it may be diverted to the clandestine manufacture of a controlled substance. In the case of a transaction reported by a broker or trader, DEA cannot suspend the transaction, but could alert authorities in the foreign country involved in the transaction of the risk of diversion. In addition, even if an importer or exporter did not have to file an initial notification – either because he is a regular importer selling to a regular customer, or an exporter selling to a regular customer -- if the newly arranged spot market sale is to a new customer, the importer or exporter must file an advance notice 15 days prior to transferring the

chemical to the new customer. As is the case under existing law, a suspension can be appealed through an administrative hearing. (See 21 U.S.C. § 971(c)(2))

If, however, the new proposed purchaser qualifies as a “regular customer” under existing law, the importer or exporter is not required to file a second advance notice 15 days prior to the transfer of the listed chemical. Rather, notice must be filed on or before the date of the transfer. Note that the second notice may occur after importation or exportation. (Brokers and traders are required to report all regulated international transactions.)

If DEA determines that a listed chemical shipment handled by a regular importer or a regular customer (including a regular customer who is substituted for the original customer listed on the original advance notification) may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the regular importer or regular customer status of such importer or customer and may suspend the shipment. If the importer or customer (including a new proposed customer) is not a regular importer or customer, then DEA may suspend the shipment, since there would be no regular importer or regular customer status to disqualify. The procedures are set forth in the new regulatory text at 21 CFR 1313.16(d). Similarly, in the case of an export of a listed chemical that may be diverted to the clandestine manufacture of a controlled substance, DEA may disqualify the regular customer status of the transferee and suspend the shipment. See 21 CFR 1313.26(d).

Finally, within 30 days after the importation, exportation, or international transaction is completed, the importer, exporter, broker, or trader must send DEA a return declaration containing information regarding the transaction, including the name of the

transferee, date the import or export and any subsequent transfer occurred, the name of the chemical transferred, the actual quantity transferred, the container, and any other information that DEA may specify. This is a new requirement for United States importers, exporters, brokers, and traders. For importers, a single return declaration may include the information for both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer must file supplemental return declarations no later than 30 days from the date of any further distribution, until the distribution or other disposition of all chemicals imported under the import notification or any update are accounted for. In addition, if an importer, exporter, broker, or trader files a Form 486, but the transfer covered fails to take place (e.g., the import or export is canceled prior to shipment), the person must file an amended Form 486 to notify DEA of the cancellation. These additional filings will ensure that DEA has an accurate record of importations, exportations, and international transactions.

Summary of Changes made by this Final Rule

The table below provides a comparison of the previous requirements regarding imports, exports, and international transactions with the new requirements of the COME:

Table 1: Comparison of Previous and New Requirements

Requirement	Previous Rule	New Rule
Notify DEA prior to import/export/international transactions	Yes	Yes
Identify source of imports/ international transactions	Yes	Yes
Identify transferees of exports/ international transactions	Yes	Yes
Identify transferees (downstream customers) of imports	No	Yes
Notify DEA of change in transferees of exports and international transactions prior to transaction	No	Yes
Notify DEA of change in transferees (downstream customers) of imports prior to transaction	No	Yes

Notify DEA of increase in chemical quantity transferred for exports and international transactions prior to transaction	No	Yes
Notify DEA of increase in chemical quantity transferred for import transactions prior to transaction	No	Yes
File return declaration when imports/exports and international transactions are distributed	No	Yes
File subsequent return declaration if entire quantity of import not distributed within 30 days of importation	No	Yes

Specific Changes made by this Final Rule

In this final rule, DEA is incorporating the provisions of § 716 of the CMEA into Title 21 of the Code of Federal Regulations. Specific changes are discussed below.

Certain definitions relating to listed chemicals in § 1300.02 are being revised or amended. The definition of “established business relationship” is being revised to remove language regarding foreign customers; this definition is now a general definition relating to any business relationship, either import or export. Further, parts of this definition are moved to new § 1313.05, requirements of an established business relationship. The definition of “established record as an importer” is being revised by moving certain information into new § 1313.08. Finally, the definition of “regular customer” is being revised to update the cross reference.

As noted previously, § 1313.05 is added to specify requirements of an established business relationship. Information in this section was previously found in the definition of “established business relationship.”

As noted previously, § 1313.08 is added to specify requirements for establishing a record as an importer. Information in this section was previously found in the definition

of “established record as an importer.” Section 1313.15(a) is being amended to update the cross reference accordingly.

Section 1313.12, requirement of authorization to import, is amended by revising paragraph (c) to add the requirement that, to qualify for a waiver of the 15 day advance notice, not only does the importer have to be known to DEA as a regular importer, but also that the customer must meet the requirements in § 1313.05 to be regarded as a regular customer. The effect of this new requirement is that, effective [**INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN FEDERAL REGISTER**], all persons previously granted regular importer status will be required to provide advance notification of imports with information regarding transferees, even for customers that they did business with in the past. This advance notification will provide DEA the opportunity to review and approve the customer as a regular customer (see the new definition in § 1300.02 and the requirements in new § 1313.05). If the 15-day notification period elapses without DEA taking action, then that importer is granted regular importer status for all imports of that particular chemical intended for the specified customer.

Section 1313.13, contents of import declaration, is amended by requiring the importer to provide information regarding the person or persons to whom the importer intends to transfer the chemical.

Section 1313.16 is added to specify requirements regarding transfers after importation, § 1313.26 is added to specify requirements regarding transfers after exportation, and § 1313.32 is amended to specify requirements for brokers and traders regarding international transactions. These requirements specify what the U.S. importer, the U.S. exporter, or the U.S. broker or trader must do if an originally planned sale falls

through and the importer or exporter arranges a subsequent spot market sale, as explained earlier in the preamble. For brokers and traders, the situation is somewhat more complicated because the broker or trader does not control the sale. If a transaction is not completed, the broker or trader could be asked to find another buyer for the chemical or the broker or trader may not be involved in arranging the subsequent sale. If the broker or trader arranges a subsequent sale to replace the previously arranged transaction, this transaction is a new transaction and must be reported as such; a return declaration must be filed when the transaction is completed.

Sections 1313.17(a), 1313.27(a), and 1313.35(a) are added to specify the requirement that within 30 days of the completion of a transaction, the importer, exporter, broker, or trader must send DEA a return declaration containing information regarding the transaction, including the name of the transferee, date the import, export, or international transaction and any subsequent transfer occurred, the name of the chemical transferred, the actual quantity transferred, the container, and any other information that DEA may specify.

Sections 1313.17(b), 1313.27(b), and 1313.35(b) are added to specify the requirement that if an importation, exportation, or international transaction reported on a Form 486 fails to be completed, the importer, exporter, broker, or trader must file an amendment to the Form 486 to notify DEA.

Revision of DEA Form 486: Import/Export Declaration for Precursor and Essential Chemicals

To comply with the changes made to the Controlled Substances Act by the Combat Methamphetamine Epidemic Act of 2005, DEA is revising the existing DEA

Form 486, Import/Export Declaration. DEA notes that this form has not been revised or amended since its inception in 1989. Thus, this form has not kept pace with subsequent legislation including the Domestic Chemical Diversion Control Act of 1993, the Comprehensive Methamphetamine Control Act of 1996, and the Methamphetamine Anti-Proliferation Act of 2000. Therefore, some of the changes DEA is making to this form are not directly related to the CMEA. However, these changes are necessary for ease of use and clarity of the form.

Changes being made include the following:

- Changing the title of the form to: “Import/Export Declaration for List I and List II Chemicals” to more accurately characterize the use of the form.
- Adding a check box for “international transaction” in addition to existing fields for “import” and “export.”
- Adding fields for DEA registration number and company identifier, if applicable.
- Adding a field for the foreign permit number, if applicable.
- Adding check boxes for the type of submission of the form: “original,” “amended,” and “withdrawn.”
- Adding fields for the actual date and quantity imported.
- Adding fields for reporting by importers of the person to whom the listed chemical will be transferred, the downstream customer, per requirements of the CMEA.
- Adding fields regarding return declaration by importers and exporters.

- Removing the certification by the Customs District Director; this certification is now the responsibility of the importer or exporter as part of the return declaration.
- Eliminating a number of fields, including: gross weight of chemicals imported/exported; intermediate carriers; address of intermediate consignees.
- Reorganizing layout for clarity.

Implementation of this Rule

Effective **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION]**, all United States importers and exporters of List I and List II chemicals must use the revised DEA Form 486 to notify DEA of their imports and exports. This revised form will be available on the Diversion Control Program web site, <http://www.deadiversion.usdoj.gov>.

Effective **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION]**, all persons previously granted regular importer status will no longer hold that status. Every import of a List I and List II chemical must be reported to DEA not later than 15 days prior to the proposed importation. This report must include the name of the person to whom the chemical is proposed to be transferred and the amount of the chemical proposed to be transferred. DEA will evaluate each proposed importation based not only on the chemical to be imported but on the transferee information supplied by the importer as well. This process will allow for the establishment of regular customer status by transferees of United States importers, and for establishment of regular importer status by importers importing a specific listed chemical intended for sale to a specific customer.

Effective [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION], all persons importing and exporting List I and List II chemicals must provide the above discussed return declarations to DEA.

Note regarding Importation of the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine

This rulemaking addresses all List I and List II chemicals. While ephedrine, pseudoephedrine, and phenylpropanolamine are List I chemicals and are covered by these regulations, other provisions of § 721 of the Combat Methamphetamine Epidemic Act require the reporting of certain information regarding the foreign chain of distribution of these three List I chemicals. Other provisions of the Combat Methamphetamine Epidemic Act require that these three List I chemicals be imported only if there is a medical, scientific, or other legitimate purpose for these chemicals. DEA is addressing these provisions in a separate rulemaking. Persons importing ephedrine, pseudoephedrine, and phenylpropanolamine are required to comply with the provisions of this rule until such time as the rulemaking regarding provision of information about the foreign chain of distribution is promulgated. At that time, persons importing these three List I chemicals will then be subject to those additional requirements.

Further, since the Combat Methamphetamine Epidemic Act requires that these three List I chemicals be imported only if there is a medical, scientific, or other legitimate purpose for these chemicals, DEA must establish import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. DEA is addressing these provisions in separate rulemakings.

Regulatory Certifications

Administrative Procedure Act (5 U.S.C. 553)

The Administrative Procedure Act (APA) generally requires agencies to publish a notice of proposed rulemaking and allow for a period of public comment prior to implementing new rules. The APA also provides, however, that agencies can be excepted from these requirements when “the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” (5 U.S.C. § 553(b)(B)).

DEA has concluded that “good cause” exists to promulgate this rule as a final rule rather than a proposed rule because the mandates of the CMEA were set forth in such detail as to be self-implementing. The changes announced in this final rule render DEA’s regulations consistent with the new provisions of the CMEA. Since DEA is without authority to revise this rule based on public comments, DEA finds that notice and opportunity for comment are unnecessary and impracticable under the APA (5 U.S.C. § 553(b)(B)).

DEA is cognizant of the fact that exceptions to the APA’s notice and comment procedures are to be “narrowly construed and only reluctantly countenanced.” *Am. Fed’n of Gov’t Employees v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981) (quoting *New Jersey Dep’t of Env’tl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980)). Based on the detailed requirements set forth in the CMEA which give no discretion in their implementation, however, DEA finds that the invocation of the “good cause” exception, and the issuance of this rule as a final rule, is justified.

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. § 605(b)). The RFA applies to rules that are subject to notice and comment. Because this rule is simply codifying statutory provisions, DEA has determined, as explained above, that public notice and comment are not necessary. Consequently, the RFA does not apply.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is “a significant regulatory action.” Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is codifying statutory provisions and involves no agency discretion. This statutory change imposes minimal costs on United States importers, exporters, brokers, and traders; they simply have to file a form with DEA in advance of spot market transactions. They must also provide a return declaration after the import or export has occurred.

Paperwork Reduction Act

As discussed previously, the Drug Enforcement Administration is revising an information collection by revising the information collected on DEA Form 486: Import/Export Declaration for List I and List II Chemicals. [OMB information collection 1117-0023] Those changes have been discussed above, and are necessary for DEA to implement the provisions of the Combat Methamphetamine Epidemic Act of 2005.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with review procedures of the Paperwork

Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537.

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Your comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) Type of Information Collection: revision of an existing collection.

(2) Title of the Form/Collection: Import/Export Declaration for List I and List II Chemicals.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:

Form Number: DEA Form 486.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) Affected public who will be asked or required to respond, as well as a brief abstract:

Primary: business or other for-profit.

Other: none.

Abstract: Persons importing, exporting, and conducting international transactions with List I and List II chemicals must notify DEA of those transactions in advance of their occurrence, including information regarding the person(s) to whom the chemical will be transferred and the quantity to be transferred. For importations, persons must also provide return declarations, confirming the date of the importation and transfer, and the amounts of the chemical transferred. This information is used to prevent shipments not intended for legitimate purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:

	Number of Respondents	Number of Responses	Average time per Response	Total Hours
Form 486 (export)	225	7,917	0.2 hour (12 minutes)	1,583.4 hours
Form 486 (export return declaration)	225	7,917	0.08 hour (5 minutes)	659.75 hours
Form 486 (import)	216	2,278	0.25 hour (15 minutes)	569.5 hours
Form 486 (import return declaration)*	216	2,506	0.08 hour (5 minutes)	208.8 hours
Form 486 (international transaction)	9	111	0.2 hour (12 minutes)	22.2 hours
Form 486 (international transaction return declaration)	9	111	0.08 hour (5 minutes)	9.25 hours
Quarterly reports for	110	440	0.5 hour (30 minutes)	220 hours

imports of acetone, 2-butanone, and toluene				
Total	225			3,272.9 hours

* DEA assumes 10% of all imports will not be transferred in the first thirty days and will necessitate submission of a subsequent return declaration.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA estimates that this collection will take 3,272.9 hours.

If additional information is required, contact: Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW, Washington, D.C. 20530.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects

21 CFR part 1300

Chemicals, Drug traffic control.

21 CFR part 1313

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR parts 1300 and 1313 are amended as follows:

PART 1300--DEFINITIONS

1. The authority citation for part 1300 continues to read as follows:

AUTHORITY: 21 U.S.C. 802, 871(b), 951, 958(f).

2. Section 1300.02 is amended by revising paragraphs (b)(12), (b)(13), and (b)(25)

to read as follows:

§ 1300.02 Definitions related to listed chemicals.

* * * * *

(b) * * *

(12) The term *established business relationship* means the regulated person has imported or exported a listed chemical at least once within the past six months, or twice within the past twelve months from or to a foreign manufacturer, distributor, or end user of the chemical that has an established business with a fixed street address. A person or business that functions as a broker or intermediary is not a customer for purposes of this definition.

(13) The term *established record as an importer* means that the regulated person has imported a listed chemical at least once within the past six months, or twice within the past twelve months from a foreign supplier.

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(25) The term *regular customer* means a person with whom the regulated person has an established business relationship for a specified listed chemical or chemicals that has been reported to the Administration subject to the criteria established in part 1313 of this chapter.

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**PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II
CHEMICALS**

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

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

4. Revise the title of part 1313 to read as set forth above.

5. Section 1313.05 is added to read as follows:

§ 1313.05 Requirements for an established business relationship.

To document that an importer or exporter has an established business relationship with a customer, the importer or exporter must provide the Administrator with the following information in accordance with the waiver of 15-day advance notice requirements of §1313.15 or §1313.24:

(a) The name and street address of the chemical importer or exporter and of each regular customer;

(b) The telephone number, contact person, and where available, the facsimile number for the chemical importer or exporter and for each regular customer;

(c) The nature of the regular customer's business (i.e., importer, exporter, distributor, manufacturer, etc.), and if known, the use to which the listed chemical or chemicals will be applied;

(d) The duration of the business relationship;

(e) The frequency and number of transactions occurring during the preceding 12-month period;

(f) The amounts and the listed chemical or chemicals involved in regulated transactions between the chemical importer or exporter and regular customer;

(g) The method of delivery (direct shipment or through a broker or forwarding agent); and

(h) Other information that the chemical importer or exporter considers relevant for determining whether a customer is a regular customer.

6. Section 1313.08 is added to read as follows:

§ 1313.08 Requirements for establishing a record as an importer.

To establish a record as an importer, the regulated person must provide the Administrator with the following information in accordance with the waiver of the 15-day advance notice requirements of §1313.15:

(a) The name, DEA registration number (where applicable), street address, telephone number, and, where available, the facsimile number of the regulated person and of each foreign supplier; and

(b) The frequency and number of transactions occurring during the preceding 12 month period.

7. Section 1313.12 is amended by revising paragraph (c) to read as follows:

§ 1313.12 Requirement of authorization to import.

* * * * *

(c) The 15-day advance notification requirement for listed chemical imports may be waived for the following:

(1) Any importation that meets both of the following requirements:

(i) The regulated person has satisfied the requirements for reporting to the Administration as a regular importer of the listed chemicals.

(ii) The importer intends to transfer the listed chemicals to a person who is a regular customer for the chemical, as defined in § 1300.02 of this chapter.

(2) A specific listed chemical, as set forth in paragraph (f) of this section, for which the Administrator determines that advance notification is not necessary for effective chemical diversion control.

* * * * *

8. Section 1313.13 is amended by adding paragraph (c)(5) to read as follows:

§ 1313.13 Contents of import declaration.

* * * * *

(c) * * *

(5) The name, address, telephone number, and where available, the facsimile number of the person or persons to whom the importer intends to transfer the listed chemical and the quantity to be transferred to each transferee.

9. Section 1313.15 is amended by revising paragraph (a) to read as follows:

§ 1313.15 Waiver of 15-day advance notice for regular importers.

(a) Each regulated person seeking designation as a “regular importer” shall provide, by certified mail return receipt requested, to the Administration such information as is required under § 1313.08 documenting their status as a regular importer.

* * * * *

10. Section 1313.16 is added to read as follows:

§ 1313.16 Transfers following importation.

(a) In the case of a notice under § 1313.12(a) submitted by a regulated person, if the transferee identified in the notice is not a regular customer, the importer may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under § 1313.12(a) or (d) is submitted to the Administration, if circumstances change and the importer will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the importer must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Administration, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under § 1313.12(a) or (d).

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the importer involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in § 1313.12(a) or (d) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§ 1313.51—1313.57, order the suspension of the transfer of the listed chemical by the importer involved, except for a transfer to a regular customer, on the ground that the chemical may

be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the DEA ordering the suspension before the expiration of the 15-day period with respect to the importation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph, disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the importer, the importer may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an importer transfers a listed chemical.

11. Section 1313.17 is added to read as follows:

§ 1313.17 Return declaration or amendment to Form 486 for imports.

(a) Within 30 days after a transaction is completed, the importer must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify. A single return declaration may include the particulars of both the importation and distribution. If the importer has not distributed all chemicals imported by the end of the initial 30-day period, the importer must file supplemental

return declarations no later than 30 days from the date of any further distribution, until the distribution or other disposition of all chemicals imported under the import notification or any update are accounted for.

(b) If an importation for which a Form 486 has been filed fails to take place, the importer must file an amended Form 486 notifying the Administration that the importation did not occur.

12. Section 1313.26 is added to read as follows:

§ 1313.26 Transfers following exportation.

(a) In the case of a notice under § 1313.21(a) submitted by a regulated person, if the transferee identified in the notice, i.e., the foreign importer, is not a regular customer, the regulated person may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the notice is submitted to the Administration.

(b) After a notice under § 1313.21(a) is submitted to the Administration, if circumstances change and the exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the exporter must update the notice to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to the Administration, except that the 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent

and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(c) In the case of a transfer of a listed chemical that is subject to a 15-day restriction, the transferee involved shall, upon the expiration of the 15-day period, be considered to qualify as a regular customer, unless the Administration otherwise notifies the exporter involved in writing.

(d) With respect to a transfer of a listed chemical with which a notice or update referred to in § 1313.21(a) is concerned:

(1) The Administration—

(i) May, in accordance with the same procedures as apply under §§ 1313.51—1313.57, order the suspension of the transfer of the listed chemical by the exporter involved, except for a transfer to a regular customer, on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance (without regard to the form of the chemical that may be diverted, including the diversion of a finished drug product to be manufactured from bulk chemicals to be transferred), subject to the DEA ordering the suspension before the expiration of the 15-day period with respect to the exportation (in any case in which such a period applies); and

(ii) May, for purposes of this paragraph, disqualify a regular customer on that ground.

(2) From and after the time when the Administration provides written notice of the order under paragraph (d)(1)(i) of this section (including a statement of the legal and factual basis for the order) to the exporter, the exporter may not carry out the transfer.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

13. Section 1313.27 is added to read as follows:

§ 1313.27 Return declaration or amendment to Form 486 for exports.

(a) Within 30 days after a transaction is completed, the exporter must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify.

(b) If an exportation for which a Form 486 has been filed fails to take place, the exporter must file an amended Form 486 notifying the Administration that the exportation did not occur.

14. Section 1313.32 is amended by adding paragraphs (d) and (e) to read as follows:

§ 1313.32 Requirement of authorization for international transactions.

* * * * *

(d) After a notice under paragraph (a) of this section is submitted to the Administration, if circumstances change and the exporter will not be transferring the listed chemical to the transferee identified in the notice, or will be transferring a greater quantity of the chemical than specified in the notice, the broker or trader must update the notice to identify the most recent prospective transferee or the most recent quantity or

both (as the case may be). The preceding sentence applies with respect to changing circumstances regarding a transferee or quantity identified in an update to the same extent and in the same manner as the sentence applies with respect to changing circumstances regarding a transferee or quantity identified in the original notice under paragraph (a) of this section.

(e) For purposes of this section:

(1) The term *transfer*, with respect to a listed chemical, includes the sale of the chemical.

(2) The term *transferee* means a person to whom an exporter transfers a listed chemical.

15. Section 1313.35 is added to read as follows:

§ 1313.35 Return declaration or amendment to Form 486 for international transactions.

(a) Within 30 days after a transaction is completed, the broker or trader must send to the Administration a return declaration containing particulars of the transaction, including the date, quantity, chemical, container, name of transferees, and any other information as the Administration may specify.

(b) If a transaction for which a Form 486 has been filed fails to take place, the broker or trader must file an amended Form 486 notifying the Administration that the transaction did not occur.

Dated:

Michele M. Leonhart

Deputy Administrator