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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1309, 1310, 1313, and 1314

[Docket No. DEA-485]

RINs 1117-AB05 and 1117-AB06

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

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: In March 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA). The Drug Enforcement Administration (DEA) promulgated an Interim Final Rule (IFR) on September 26, 2006 (with a technical correction on October 13, 2006), under Docket Number DEA-291I, to implement the retail sales provisions of the CMEA. Additionally, on April 9, 2007, DEA promulgated an IFR, under Docket Number DEA-292I, to implement section 716 of the CMEA, which required additional reporting for import, export, and international transactions involving all list I and list II chemicals. DEA is finalizing these rulemakings in one action. This final rule adopts, with one technical change, the corrected September 2006 IFR, and adopts, without change, the April 2007 IFR.

DATES: Effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The effective date of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], for the interim final rules

published September 26, 2006 (71 FR 56009) and April 9, 2007 (72 FR 17401), is confirmed.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (571) 362-3261.

SUPPLEMENTARY INFORMATION:

I. Background

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). The Drug Enforcement Administration (DEA) published interim final rules (IFRs) on September 26, 2006 (71 FR 56008) – with a technical correction on October 13, 2006 (71 FR 60609) – and April 9, 2007 (72 FR 17401) to implement certain provisions of the CMEA.

On December 30, 2016, DEA published a final rule “Revision of Import and Export Requirements for Controlled Substances, Listed Chemicals, and Tableting and Encapsulating Machines, Including Changes To Implement the International Trade Data System (ITDS); Revision of Reporting Requirements for Domestic Transactions in Listed Chemicals and Tableting and Encapsulating Machines; and Technical Amendments.” 81 FR 96992. This final rule included further amendments to amendments implemented by the September 2006 and April 2007 IFRs.

A. September 2006 IFR

The CMEA established new requirements for the retail sale of products containing the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine

which may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug. These products, known under the CMEA as scheduled listed chemical products, can be used to manufacture methamphetamine illegally. To implement those requirements, the September 2006 IFR established daily and 30-day limits on the sales of scheduled listed chemical products to individuals, and established recordkeeping on most retail sales. More detailed information can be found in the preamble to the September 2006 IFR. On October 13, 2006, at 71 FR 6069, a technical correction was published for Table 3 on page 56014 in the September 2006 IFR.

B. April 2007 IFR

The April 2007 IFR implemented section 716 of the CMEA to require additional reporting for import, export, and international transactions involving all list I and list II chemicals, and in so doing, closed a loophole in the regulatory system. Briefly, section 716 of the CMEA (21 U.S.C. 971 as amended) extends the current reporting requirements – as well as the current exemptions for regular importers and regular customers – to post-import and post-export transactions of list I and list II chemicals. With implementation of this IFR, importers, exporters, brokers, and traders are required to notify DEA, before the transaction is to take place, of certain information regarding their downstream customers. This person is referred to as the “transferee” of the United States importer, exporter, broker, or trader. Notification occurs on a new DEA Form 486.¹ If the transferee changes, or the quantity of the chemical is increased after initial notification to

¹ DEA Form 486 is titled “Import/Export Declaration for List I and List II Chemicals” and is available online at www.deadiversion.usdoj.gov.

DEA, the importer, exporter, broker, or trader must file an amended DEA Form 486 with DEA. 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.

C. Updates to September 2006 and April 2007 IFRs due to the ITDS Rule

On December 30, 2016, DEA published the ITDS rule. 81 FR 96992. The ITDS rule was scheduled to become effective January 30, 2017. However, the effective date was delayed until March 21, 2017. 82 FR 8688.

The ITDS rule updated DEA's regulations for the import and export of tableting and encapsulating machines, controlled substances, and listed chemicals, and its regulations relating to reports required for domestic transactions in listed chemicals, gammahydroxybutyric acid, and tableting and encapsulating machines. The amendments clarified certain policies, reflected current procedures and technological advancements, and implemented Executive Order (EO) 13659 on streamlining the export/import process. The ITDS rule additionally implemented changes to the Controlled Substances Import and Export Act for reexportation of controlled substances among members of the European Economic Area made by the Improving Regulatory Transparency for New Medical Therapies Act (Pub. L. 114-89). The rule also included additional substantive and technical and stylistic amendments.

The ITDS rule included further changes to certain amendments implemented by the September 2006 and April 2007 IFRs. This current final rule does not make any changes to those further amendments.

II. Discussion of Public Comments Received on September 2006 IFR

DEA received 18 comments on the September 2006 IFR. Commenters included trade associations for convenience stores and grocery stores, a law firm, a pharmaceutical organization, a non-pharmaceutical organization, individual pharmacists, and retailers.

Logbooks: Five commenters objected to the requirement for a bound logbook for paper records. One commenter stated that DEA exceeded its authority in requiring that the logbook be bound, because the CMEA includes no such mandate. Other commenters focused on practical problems with bound logbooks. One chain drug store stated that to comply with State requirements to check the logbooks for the past 30 days, it used alphabetical logs that allowed for pages to be inserted. Other commenters stated that available bound logbooks do not meet DEA requirements, and that retailers would have to order customized books at considerable expense or customize blank logbooks by hand. One commenter stated that spiral logbooks should be acceptable if they have page numbers. Other commenters recommended that DEA adopt more flexible requirements. One suggested that DEA only require that the pages of the logbook not be readily removable, altered, or copied without the change being detectable. Another commenter stated that DEA should simply require tamper-evident logs. This commenter stated that DEA had presented no information about why tamper-evident logbooks are important to thwart illegal use of scheduled listed chemical products.

DEA Response: In its regulations implementing the CMEA, DEA required bound logbooks for paper logs because the other types of logbooks suggested can be tampered with simply by removing pages. Tamper-proof paper would prevent alteration of the records, but would not prevent removal of pages. DEA noted that pharmacies are

required to maintain bound logbooks for sales of certain schedule V controlled substances. DEA and the CMEA also allowed regulated sellers to maintain logs electronically.

In October 2008, the President signed the Methamphetamine Production Prevention Act of 2008 (MPPA) (Pub. L. 110-415). The MPPA clarified the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. The MPPA allows regulated sellers to choose between maintaining a written or electronic logbook. For regulated sellers who choose to maintain a written logbook, the MPPA requires that the logbook be bound.² However, with respect to electronic logbook systems, the MPPA provides greater flexibility for sellers of scheduled listed chemical products. DEA implemented the provisions of the MPPA in a final rule published December 1, 2011. 76 FR 74696.

Privacy Issues: Five commenters were concerned about the requirements related to protecting information entered into logbooks from exposure. As a practical matter, these commenters focused on paper logs, where previous customer entries may be seen by subsequent purchasers. Commenters asked DEA to define what “accessed” and “shared” mean, and to indicate that “shared” does not mean incidental disclosure to other customers using the same page.

Associations representing retailers stated that DEA should state that the records are not “protected health information” subject to the Health Insurance Portability and Accountability Act (HIPAA). One commenter noted that States have decided that the

² Pub. L. 110-415, Sec. 2, “Clarifications Regarding Signature Capture and Retention for Electronic Methamphetamine Precursor Logbook Systems.”

logs are not HIPAA protected. Another commenter stated that the log information is not sensitive; customers have been purchasing these products off the shelves for years without any expectation of privacy. The products can be used for a number of conditions and, therefore, reveal little about the purchaser's condition. This commenter also stated that limiting the log to a single entry per page would be expensive. An organization representing pharmacists stated that the logs should be considered subject to HIPAA and that customers should see only their own information.

One retailer asked DEA to clarify what methods are acceptable to prevent other customers from seeing the information. One pharmacist stated that requesting a form of identification and entering data into the log was an invasion of privacy. Two pharmacists noted that the process is time consuming.

DEA Response: The CMEA provides requirements regarding the protection of logbook information. In regard to the disclosure of collected information, the CMEA established restrictions on disclosure of information in logbooks to protect the privacy of individuals who purchase scheduled listed chemical products. 21 U.S.C. 830(e)(1)(C).

The logbook privacy protections set forth by the CMEA are implemented by DEA to closely resemble the language in the CMEA.³ By adopting the statutory language regarding protection of logbooks in the regulations virtually without change, DEA has provided regulated sellers the greatest flexibility possible to ensure that customer information is protected, without dictating specific requirements.

³ DEA regulations regarding logbook privacy protections also include a provision which states that “[a] regulated seller who in good faith releases information in a logbook to Federal, State, or local law enforcement authorities is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.” 21 CFR 1314.45(c).

The United States Department of Health and Human Services' Office of Civil Rights enforces HIPAA,⁴ and it is the responsibility of covered entities (including pharmacies) to ensure that all aspects of their business practices are HIPAA compliant.⁵ The covered entity is responsible for adequate safeguards and policies to ensure that protected health information in logbooks is not disclosed. DEA is not responsible for ensuring that such entities have the necessary safeguards in place to ensure that protected health information is not disclosed. DEA does not have authority to enforce HIPAA. However, 21 CFR 1314.45 provides privacy protections to purchasers of scheduled listed chemical products by restricting the disclosure of information collected in logbooks. Scheduled listed chemical products are sold in a wide variety of settings, from large retail chains where information is captured at general checkout lines to small pharmacies where information is captured at the pharmacy counter. To define the terms "access" and "share" in relation to logbook information could unnecessarily and adversely impact the sales of scheduled listed chemical products by regulated sellers.

Although the process requires additional time, the CMEA required that the purchaser sign the logbook, enter the purchaser's name and address, the date and time of sale, and that the regulated seller enter the name and quantity of the product sold. The CMEA further required that the regulated seller determine that the name on the identification presented by the purchaser corresponds to the name entered by the

⁴ The HIPPA Privacy Rule implemented national standards to protect personal health information which requires covered entities to implement appropriate administrative, technical, and physical safeguards to reasonably protect personal health information (with limited exceptions including information transmitted in writing, orally, or electronic form) from intentional or unintentional use or disclosure. See 67 FR 53182, 53193 (Aug. 14, 2002).

⁵ https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/all-cases/index.html?language=en#case20_

purchaser in the logbook. DEA had no discretion in the implementation of these requirements.

Other Logbook Issues: One association stated that the log entry requirements should be more flexible. Other than the signature, the commenter believed that DEA should not specify who has to enter the other data. The commenter suggested that stickers could be used to identify the product information other than the number of containers. Another retail association stated that DEA should allow others to enter the data when the purchaser is unable to do so (e.g., because of a disability).

DEA Response: The CMEA required that the purchaser enter certain specific information as specified in 21 U.S.C. 830(e). DEA implemented those provisions in the September 2006 IFR. DEA sought to balance its statutory obligations while recognizing that with electronic logbooks, it may be difficult or impossible for some purchasers to enter the required information. To ensure that all persons were able to purchase scheduled listed chemical products at retail, DEA made an allowance at 21 CFR 1314.30(c) that if the purchaser were feasibly unable to do so, the regulated seller may ask for and enter the information electronically. This is similar to the regulated seller entering the information when the information must be entered into an electronic system that is not easily accessible to the customer.

Subsequent to DEA's implementation of the CMEA, the MPPA was passed, revising the information entry and signature requirements for electronic logbook systems permitted for the retail sale of scheduled listed chemical products. The MPPA allows for flexibility with its provisions relating to log entry requirements. Under the MPPA, regulated sellers of scheduled listed chemical products may choose from several options

relating to how purchaser signatures may be obtained and how transactions may be recorded. 21 U.S.C. 830(e)(1)(A)(iv). DEA published a final rule on December 1, 2011, which implemented the MPPA. 76 FR 74696.

Federal/State Issues: Several commenters raised issues related to different Federal and State laws related to retail sales of scheduled listed chemical products. One association asked DEA to provide guidance on how to reconcile conflicting requirements on logbooks. The commenter asked whether a regulated seller would have to maintain two separate logbooks if State law requires different information than Federal law. Another association stated that DEA should allow the use of a single logbook to capture information for both requirements. The association asked DEA to provide a State-by-State analysis to let regulated sellers know which provisions apply in each State. Another association stated that compliance with a State rule that is as stringent or more stringent than DEA's should satisfy DEA's requirements. One chain pharmacy stated that DEA should allow electronic capture of State information and manual capture of additional DEA elements rather than require two separate sets of logs.

DEA Response: Regulated sellers may use a single logbook for capturing Federal and State requirements provided that the data entered includes all of the elements required under the CMEA. If the data required by Federal law and State law is so markedly different that it cannot be merged easily, or if regulated sellers wish to do so for other reasons, regulated sellers may also use separate systems. If a State's requirements include all of the CMEA's requirements, a separate logbook need not be created. DEA, however, does not have the authority to alter the CMEA requirements.

Warning Notice: The CMEA requires that regulated sellers post a warning notice to inform customers that providing false information is a violation of Federal law. One commenter stated that DEA should recognize that any of the following meets the requirements for providing notice: displaying the notice under glass near the logbook; putting it on the wall behind the logbook; or putting it on the cover of the logbook. The commenter also recommended that DEA allow mandated State notices to replace the Federal notice, because multiple warning notices can be confusing to the customer.

DEA Response: The CMEA mandated the warning notice; a State notice cannot substitute for the statutorily required warning that entering false statements or misrepresentations is a violation of Federal law. The regulation for placement of the notice provides regulated sellers with flexibility on placement of the notice. The only requirement is that the notice either be included in the written or electronic logbook, or displayed by the logbook. 21 CFR 1314.30(d).

Photographic Identification: One association stated that DEA should clarify that regulated sellers are only required to check the photographic identification to ensure that the name entered into the log is the same as the name on the identification and that the date and time are correct. In addition, the association claimed that the CMEA does not require a regulated seller to refuse to sell the product if the name is not correct. The commenter noted that there may be legitimate reasons for discrepancies (e.g., such as name or address change since the issuance of the identification). In addition, clerks could be at risk if they challenged a customer.

DEA Response: The CMEA required that the regulated seller determine that the name entered into the logbook matches the name on the identification presented. The

prospective purchaser must provide an appropriate identification card and signature and the seller must confirm the identification provided matches the information entered into the logbook.⁶

DEA recognizes that there will be times when names listed on an identification may not correspond to information entered into logbooks, due to marriage, name change, etc. However, DEA emphasizes that regulated sellers are required to comply with the CMEA, including not selling a product to customers if the name the customer entered into the logbook does not match the identification presented.

The MPPA amended section 310(e)(1)(A) of the CSA (21 U.S.C. 830(e)(1)(A)) to provide flexibility in the creation and maintenance of electronic logbooks, while retaining the CMEA's basic requirement that the regulated seller determine that the name entered into the logbook matches the name on the identification presented: In the case of a sale to which the [logbook requirement] applies, the seller does not sell such a product unless the sale is made in accordance with the following: The logbook maintained by the seller includes the prospective purchaser's name, address, and the date and time of the sale, as follows:

⁶ The CMEA provision at 21 U.S.C. 830(e)(1)(A)(iv) stated "In the case of a sale to which the [logbook] requirement . . . applies, the seller does not sell such a product unless . . . the prospective purchaser . . . 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 . . . signs the logbook and enters in the logbook his or her name . . . and the seller . . . determines that the name entered in the logbook corresponds to the name provided on such identification"

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. If the seller enters the information, the prospective purchaser must verify that the information is correct.⁷

Identification for Mail-Order Distributors: An Internet pharmacy stated that requiring a photographic identification for mail-order sales was not helpful. The retailer collects the purchaser's name, credit card name, billing address, shipping address, and e-mail address. The retailer is not in a position to verify the photographic identification. In addition, a copy of a photographic identification can be manipulated to change information. The commenter believed that the requirement is an unreasonable burden on the consumer that does little to prevent illicit sales.

DEA Response: The CMEA intends for the retailer to verify the identity of the customer, whether that retailer is a regulated seller or a mail-order distributor. For regulated sellers, the CMEA was clear and specific in its requirements.⁸ The purchaser is required to present a photographic identification or other permissible form of identification. 21 U.S.C. 830(e)(1)(A)(iv)(I)(aa). The regulated seller must then “determine that the name entered in the logbook corresponds to the name provided on such identification...” 21 U.S.C. 830(e)(1)(A)(iv)(III)(aa).⁹

⁷ Pub. L. 110-415, Sec. 2, “Clarifications Regarding Signature Capture and Retention for Electronic Methamphetamine Precursor Logbook Systems.”

⁸ In addition to the CMEA, section 2 of the Combat Methamphetamine Enhancement Act of 2010 (MEA) (Pub. L. 111-268) requires that “the Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for certifications of regulated sellers...” DEA published an IFR on April 13, 2011, which implemented this MEA section. 76 FR 20518.

⁹ This statutory cite denotes the provision in the MPPA. This requirement in the CMEA was denoted at 21 U.S.C. 830(e)(1)(A)(iv)(II)(aa).

Mail-order distributors are no less regulated. While mail-order distributors do not conduct face-to-face transactions, they still need to confirm purchaser identity. The CMEA states that mail-order distributors “shall, prior to shipping the product, confirm the identity of the purchaser in accordance with procedures established by the Attorney General.” 21 U.S.C. 830(e)(2)(A). In its regulations implementing the CMEA, DEA interpreted the requirement to “confirm the identity of the purchaser” to mean that mail-order distributors must “receive from the purchaser a copy” of a photographic identification or other permissible form of identification. 21 CFR 1314.105(a).

The requirement that mail-order distributors receive a copy of the purchaser’s photographic identification is perhaps even more important due to the anonymity of the transactions. Providing a copy of a photographic identification issued by a Federal or the State government, or a copy of another document permissible for identification purposes, lends credence to the name and address given by phone, fax, or Internet during the order process. It is no more unreasonable to require the mail-order distributor to compare the name and address on the identification with the name and address given on the order, than it is for a regulated seller to compare the information presented by the purchaser with the information entered into the logbook as part of the face-to-face transaction.

Daily and 30-day Limits: Two commenters raised questions about the daily and 30-day limits set in the CMEA. Both stated that DEA should include the CMEA language to clarify that retailers are not expected to check the logbooks to determine if a customer is exceeding the daily or 30-day limits. One of the commenters stated that the 30-day limit applies only to the purchaser, not the retailer. The same commenter stated that DEA should waive the 30-day and daily limits for mail-order sales if the retailer has

a system in place to prevent a customer from exceeding the CMEA limits in a year with monthly reports to DEA. This commenter also recommended that the daily limit should be a calendar day, not any 24-hour period.

DEA Response: DEA has not included the language from the statute because it is part of the penalty provisions, which are not included in the regulations. DEA has no authority to waive the requirements for mail-order distributors, including the daily and 30-day sales limits, regardless of any steps the mail-order distributor chooses to take regarding sales of scheduled listed chemical products. Finally, as discussed in the September 2006 IFR, DEA has set the 24-hour period as a calendar day.

Certification: Four associations commented on the self-certification process. Two supported the annual certification versus a more frequent process. One association noted that turnover of staff was about 130 percent a year; updating the certification for each new staff would be unnecessarily burdensome. One association suggested allowing small rural stores to submit certifications through state associations. Another association asked that companies with many stores be allowed to select a single renewal date so that the stores are not recertifying at different times. One association asked DEA to clarify whether chains had the option to certify stores individually or in batches. One association noted that many small businesses do not have computers or Internet access, making the web-based certification a burden for them.

DEA Response: The self-certification requires that the regulated seller attest to the truthfulness of its certification; the regulated seller is liable for misstatements. Therefore, DEA cannot allow third-party associations to file the certification statements on behalf of regulated sellers. Chain stores, however, may file on behalf of their

individual store locations. If a chain batch files for its stores, they will all have the same recertification date. Where regulated sellers self-certifying with DEA pursuant to the CMEA are also DEA registrants, DEA has worked to ensure that the certification expires in the same month, but not necessarily the same year, as DEA registration. DEA will continue to handle the certification process through the Internet. Even a small business owner will have a way to access the Internet through a business, home, or public computer.

Certification Signer: One retailer stated that the location manager was the appropriate person to sign the certification on behalf of the regulated seller. An association stated that DEA should revise its certification website, which includes the controlled substance rules for who is allowed to sign a registration. The commenter also recommended that a person should be allowed to sign if the person is in a position to certify that the particular location is in compliance with the requirements of the CMEA. Another association stated that DEA should clarify the level of knowledge the signer needs and provide flexibility on who is authorized to sign. Another commenter stated that the rule language regarding the person allowed to sign should be “on behalf of the regulated person or distributor” not the “regulated seller,” which is narrower.

DEA Response: DEA appreciates the comments regarding who should sign the certification on behalf of the regulated seller. Regarding the regulatory language, only regulated sellers, not regulated persons, were required to self-certify under the CMEA. The regulatory text is correct as written. In its rule implementing the Combat Methamphetamine Enhancement Act of 2010 (CMEA) (Pub. L. 111-268), DEA amended

the CFR to include three new sections pertaining to mail-order sales (1314.101, 1314.102, and 1314.103) which included the phrase “regulated person.” 76 FR 20518.

Certification Fee: Three commenters opposed a fee for certification. One pharmacist stated that pharmacies would not carry the products if they had to pay a fee. An association stated that a fee would disproportionately affect small businesses and sole proprietors, which operate on small margins. Another association objected to paying DEA to file information that DEA requires them to file.

DEA Response: DEA appreciates these comments. DEA published a final rule establishing self-certification fees for regulated sellers selling scheduled listed chemical products at retail on December 29, 2008 (73 FR 79318). In that rulemaking, DEA waived the self-certification fee for persons holding a current, valid DEA registration as a pharmacy to dispense controlled substances, and established a \$21 self-certification fee for regulated sellers of scheduled listed chemical products that are not DEA pharmacy registrants. In the final rule, DEA certified that the rule will not have a significant economic impact on a substantial number of small entities whose interests must be considered under the Regulatory Flexibility Act (RFA).

Training: Three associations raised issues related to employee training. Two indicated that DEA training material does not recognize that not all employees require training; only those who handle the product do. The commenter noted that in some stores, the information is collected at one location; the checkout clerk merely takes the payment. The commenter believed the current training is confusing. One association stated that the training implies, improperly, that the regulated seller must check the logs for daily and 30-day limits, which the CMEA does not require. The commenter also

asked DEA to remove the reference to phenylpropanolamine, which is not sold at retail as an over-the-counter drug. Another association claimed the training material needs to be revised to state that the limits apply to ephedrine and pseudoephedrine base, not to the product. An association stated that DEA should scale back the training record requirements. The commenter indicated that the CMEA does not require that all records be maintained or that employees sign an acknowledgement of training, let alone that the signed acknowledgement be maintained in the personnel record.

DEA Response: DEA appreciates the comments on the training content. DEA believes that no changes are needed to the training and the training content, as written, is necessary to ensure that employees of regulated sellers are properly trained to meet the requirements of the CMEA. In addition, DEA does not believe that the discussion of phenylpropanolamine should be removed from the training as it is a chemical covered by the CMEA. The training content provided by DEA has been utilized by industry for over 10 years. Furthermore, to reiterate CMEA requirements, all persons who either are responsible for delivering scheduled listed chemical products into the custody of purchasers or who deal directly with purchasers by obtaining payments for the products must receive training regarding the requirements of the CMEA.

21 U.S.C. 830(e)(1)(A)(vii). Regulated sellers are required to use training provided by DEA, but may augment that training with their own information if they so choose. DEA disagrees that sellers do not need to retain records of the training. Without such records, the regulated seller would not be able to document, for itself or for law enforcement that the regulated seller had complied with the rule and the CMEA by training its employees.

Availability: Two pharmacists claimed that the rule had impeded access to customers with legitimate needs. The commenters believed that most stores are not informing customers of behind-the-counter availability. One pharmacist stated that the substitutes were inferior with more side effects. The commenter claimed that the rule has not reduced illicit methamphetamine production given the Internet and other sources of the products. One individual stated that distributors are limiting the products they supply. One pharmacy customer had asked the pharmacy for a prescription for a nonprescription product; another pharmacy refused to carry them because of the logbook hassle. The commenter asked DEA to require pharmacies and distributors to provide the products.

DEA Response: DEA has no authority to require regulated sellers or distributors to carry products or to require stores to inform customers of product availability.

Costs: One chain pharmacy stated that compliance had cost it \$2.4 million to move products behind-the-counter, change signage, train workers, and print logs. An association stated that stores would need to train more than two people a year. The commenter noted that estimates of space costs ignored the limited availability of such space. The commenter noted that States require retailers to store cigarettes and lottery tickets behind the counter. Many stores have marketing and display agreements with cigarette companies. The commenter claimed that DEA rule can hurt store sales and marketing revenues. In addition, over-the-counter sales of the products spur impulse purchases of other products so that, even if the products are a small percentage of sales, loss of these sales will have a considerable impact on in-store sales. Another association stated that the rule would affect a substantial number of small entities, which have fewer resources to devote to compliance.

One commenter raised issues related to the cost of complying with the CMEA requirements, such as training, store reconfigurations, and logbooks, and estimated the total cost of implementation to be approximately \$2.26 million for a large chain pharmacy and almost \$600,000 for a medium-sized pharmacy chain. Another commenter stated that DEA's assumptions and estimates regarding annual certification and employee training, as well as for behind-the-counter storage and its effect on impulse purchases, were inadequate.

DEA Response: While the placement of these products behind-the-counter may displace some items, it opens up space on the counter and shelves for others. Similarly, while some purchasers of these products may then decide to purchase other products, the reverse is also true; for some purchasers, these would be the impulse purchases. Finally, DEA recognized the impact on small entities, but the CMEA provided no discretion to apply different rules to small businesses.

DEA has no authority to alter the behind-the-counter requirement. DEA also notes that the costs mentioned by these commenters are generalized and actual costs are unknown. For these reasons, DEA continues to believe that this rule will not have a significant economic impact on a substantial number of small entities, and has certified accordingly pursuant to the RFA, referenced below.

Other Issues: One association stated that DEA should add provisions to the rule to clarify that all retail sellers, not just registrants, are subject to the rule. The association also asked for explicit rule language to specify that prescription products are not subject to the rule.

DEA Response: The rule is already clear on both these points. The CSA, as amended by the CMEA, defines a “scheduled listed chemical product” in part as “a product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.”

21 U.S.C. 802(45)(A)(ii); 21 CFR 1300.02. Thus, DEA believes no further clarification is necessary. Nothing in the definitions of “regulated seller” (21 U.S.C. 802(46)) or “retail distributor” (21 U.S.C. 802(49)), upon which the definition of regulated seller is based, discusses or stipulates requirements regarding registration. Again, DEA does not believe that further clarification is warranted.

Definition of “unusual or excessive loss.” One commenter asked for a definition of “unusual or excessive loss.” The commenter stated that DEA should suspend enforcement until it has clarified loss reporting in another rule.

DEA Response: DEA regulation at 21 CFR 1314.15(a) does not define unusual or excessive loss. The phrase applies to a wide range of regulated persons, from small stores, to large-scale distributors, to manufacturers. The definition of unusual and excessive loss will vary too much to develop a single standard or definition applicable to a wide range of regulated persons.

Definition of retail distributor: One commenter stated that the definition of retail distributor as codified in the regulations should include ephedrine, as it does in the CSA.

DEA Response: DEA appreciates the commenter noting this inconsistency. The CSA definition of “retail distributor,” as amended by the CMEA, does include

ephedrine.¹⁰ The September 2006 IFR revised the definition of “retail distributor” at 21 CFR 1300.02(b)(29) to conform with the CMEA provision; however, this regulatory definition inadvertently omitted “ephedrine.” In January 2012, DEA issued a technical amendments rule which removed the numbers for each definition in 21 CFR 1300.02(b). 77 FR 4228. This final rule revises the definition of “retail distributor” at 21 CFR 1300.02(b) to include ephedrine.

Lack of notice and comment: An Internet retailer objected to the lack of notice and comment. The commenter stated that Congress did not intend to require photographic identification of purchasers for mail-order, so the rule was not an extension of Congressional intent. The commenter believed that notice and comment would also have given retailers time to prepare for compliance; the commenter indicated that the requirement for photographic identification requires software and process changes that take time. The commenter believed that it is unfair to the company and consumers to make this change without comment. Another commenter noted that the IFR was published only four days before the compliance date, which did not give sellers time to comply.

DEA Response: In regards to mail-orders, the CMEA requires the purchaser to present a Federal or State government issued identification card that provides a photograph or a document that with respect to identification is considered acceptable pursuant to 8 CFR 274a.2(b)(1)(v)(A) and 274a.2(b)(1)(v)(B). The regulated person

¹⁰ “Retail distributor” is defined as a grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to ephedrine, pseudoephedrine, or phenylpropanolamine products are limited almost exclusively to sales for personal use, both in sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. 21 U.S.C. 802(49)(A).

must verify that the name and address on the identification correspond to the information provided by the purchaser. DEA had a very limited period to conform its regulations to the CMEA requirements; the law was signed March 9, 2006, with a statutory deadline of September 30, 2006. The requirements of the CMEA would have gone into effect regardless of the regulations. If DEA had not published regulations when it did, procedures would not have been in place permitting persons to self-certify; thus, persons could not have legally sold scheduled listed chemical products at retail. Consequently, there was no time to seek comment prior to the CMEA deadlines, nor would comments have altered the requirements that the CMEA established. DEA conducted outreach activities to inform industry of the statutory requirements prior to the rulemaking, so they had time to come into compliance by the statutory deadlines.

Limitation of sales: One commenter suggested that sales be limited to pharmacies; Internet sales should be banned. Another commenter stated that DEA should control distributors. One asked if liquids could be used to make methamphetamine illicitly and suggested that if they cannot, sales should be limited to liquids. One pharmacist suggested that scheduled listed chemical products be listed as controlled substances.

DEA Response: The CMEA did not provide DEA authority to limit sales of scheduled listed chemical products to pharmacies. DEA already regulates distributors of scheduled listed chemical products as, prior to their retail sale, they are considered list I chemicals. As DEA has discussed in other rulemakings regarding implementation of the

CMEA,¹¹ liquid forms of scheduled listed chemical products can be used to manufacture methamphetamine illicitly, which is why Congress included all forms under the CMEA requirements. Congress did not choose to place scheduled listed chemical products in the schedules of controlled substances.

Small businesses: One commenter representing small to midsize businesses that engage in the manufacture, distribution, and sales of scheduled listed chemical products and other over-the-counter pharmaceuticals, stated that implementation of the CMEA will have a significant impact on small business. The commenter noted that small enterprises have fewer financial and material resources than their larger counterparts, thus making compliance a more expensive business expense, and that hundreds of thousands of small retailers, and their distributors, will be impacted.

DEA Response: Although DEA agrees with the commenter that the rule affects a substantial number of small entities, for the reasons previously discussed, DEA continues to believe that the rule does not have a significant economic impact on a substantial number of small entities, and has certified accordingly pursuant to the RFA, referenced below.

III. Discussion of Public Comments Received on April 2007 IFR

Request for Delay of Effective Date

DEA received comments from the regulated industry requesting the delay of the effective date of the rulemaking to allow industry more time to fully comply with the new provisions. The rule originally became effective on May 9, 2007. However, after careful

¹¹ See DEA final rule titled "Removal of Thresholds for the List I Chemicals Pseudoephedrine and Phenylpropanolamine," published in the *Federal Register* on November 20, 2007, at 73 FR 65248.

consideration of the comments received, DEA temporarily stayed the provisions of the IFR by 30 days, from May 9, 2007 to June 8, 2007. 72 FR 28601, May 22, 2007.

Other Comments Received

DEA received five substantive comments on the IFR. Commenters included chemical manufacturers and distributors and national associations representing manufacturers of chemicals and flavorings and fragrances. DEA has determined that no changes are necessary to the rule as implemented as a result of the comments received. Therefore this final rule finalizes the IFR without change. The following discussion summarizes the issues raised by commenters and DEA's response to these issues.

Interpretation of the CMEA

One commenter disagreed with DEA's requirement that the transferee be identified before the import or export can take place. This commenter agreed that, while it is clear that Congress intended that the transferee be identified before a transfer to a new customer takes place, the CMEA does not require the transferee be identified before an import or export can take place.

DEA Response: DEA disagrees with the commenter's interpretation of new section 716. Section 716 of the CMEA amended 21 U.S.C. 971 by adding a new subsection (d)(1)(A) which states that "[i]nformation provided in a notice under subsection (a) or (b) shall include the name of the person to whom the importer or exporter involved intends to transfer the listed chemical involved, and the quantity of such chemical to be transferred." Paragraph (a) of section 971 requires each regulated person who imports or exports a listed chemical to notify the Attorney General of the importation or exportation not later than 15 days before the transaction is to take place.

Paragraph (b)(1) of section 971 requires the regulated person to notify the Attorney General of an importation by a regular importer or an exportation to a regular customer at the time the transaction is to take place. Thus, paragraph (d)(1)(A) requires the identification of the transferee at the time of the provision of DEA Form 486 to DEA.

Request for Extension of Effective Date

Three commenters objected to the lack of opportunity to comment on procedures before the IFR was issued and on the 30-day effective date imposed by the IFR, stating that it would not allow industry enough time to thoroughly review the new requirements, seek clarification regarding unclear provisions, and implement procedures to comply with the new requirements. One commenter indicated that it needed additional time to modify its computer programming logic to accommodate the revisions to DEA Form 486. One commenter believed that DEA's failure to conduct notice and comment rulemaking violates the Administrative Procedure Act (APA). Two commenters requested a 90-day extension to the effective date to allow the industry more time to come into compliance with the new rules.

DEA Response: After careful consideration of the concerns expressed by these commenters, DEA temporarily stayed certain provisions of the IFR published April 9, 2007. The temporary stay of certain provisions was published May 22, 2007 (72 FR 28601). Specifically, DEA temporarily stayed the following provisions:

- The waiver of the 15-day advance notification requirement for importations of a listed chemical for which the importer intends to transfer the listed chemical to a person who is a regular customer of the chemical;

- The requirement that importers, exporters, brokers, and traders notify DEA of the transferee of the listed chemical;
- The requirement that importers, exporters, brokers, and traders amend DEA Form 486 if the transferee changes or the quantity of the chemical to be transferred increases; and
- The requirement that importers, exporters, brokers, and traders file return declarations regarding importations, exportations, and international transactions with DEA.

These provisions were already in effect because of their inclusion in the CMEA; however, their implementation was temporarily stayed until June 8, 2007. The temporary stay applied only to those provisions implemented by section 716 of the CMEA. All other provisions regarding the importation, exportation, and international transactions involving list I and list II chemicals remained in full force and effect.

DEA did not conduct a Notice of Proposed Rulemaking (NPRM) with an opportunity for comment because the CMEA set forth the provisions in such detail as to be self-implementing and gave no discretion in its implementation. DEA is merely codifying the statutory provisions. Also, Congress was clear in its intent that these provisions be implemented quickly, which precluded full notice and comment rulemaking. DEA did seek comments in the IFR and is responding to these comments in this Final Rule.

With respect to the commenter's allegation that DEA violated the notice and comment requirement of the APA, DEA notes that it provided an extensive discussion of the "good cause" exception to this requirement in its April 2007 IFR. DEA

acknowledged that the good cause exception to the APA's notice and comment procedures is to be "narrowly construed and only reluctantly countenanced." 72 FR 17405. DEA reiterates its position that because the CMEA's provisions regarding additional reporting for import, export, and international transactions involving list I and list II chemicals were so specific, DEA had no discretion in their implementation. DEA merely codified in its regulations that which had been explicitly required by Congress in section 716 of the CMEA. DEA believes that its use of the good cause exception to the APA's notice and comment requirements was entirely appropriate in this case.

Transferee Information

Three commenters stated that the IFR did not address the situation where, at the time of import or export, the importer or exporter does not intend to transfer the listed chemical to any person. Instead, the importer or exporter intends to transfer it to themselves either for stock purposes or for later distribution to transferees (downstream customers) that will be identified. One commenter described its (first in, first out) method of handling inventory and requested clarification on whether it can continue to follow that practice, since the exact material imported for a particular customer may not always be distributed to that customer. Another commenter speculated that DEA intended that the importer could list as the transferee another legal entity or listed chemical business activity. In this case importers could list their own manufacturer or distributor registration information. Another commenter suggested that, at the time of import or export of listed chemicals, if a transferee (downstream customer) has not been identified, DEA Form 486 space for transferee should be completed with the name of the importer. This would reflect the importer's intention to hold the listed chemicals in

inventory. When the importer, exporter, broker, or trader later identifies a proposed transferee, then they must file an amended DEA Form 486 reporting the name of the person to whom the importer or exporter involved intends to transfer the listed chemical, and the quantity of such chemical to be transferred. Commenters requested that DEA clarify precisely when and how the identity of the transferee (downstream customer) must be provided if it is not known at the time of import.

DEA Response: The CMEA is clear in its plain language. As discussed above, at the time the advance notification (DEA Form 486) is provided to DEA, the importer, exporter, broker, or trader “shall include the name of the person to whom the importer or exporter involved intends to transfer the listed chemical involved, and the quantity of such chemical to be transferred.” DEA cannot change this requirement. However, DEA notes that the importer or exporter can change the name of the transferee included on DEA Form 486 simply by submitting an amended DEA Form 486 to DEA. For exports, a chemical may be exported from a United States facility of a company to a foreign facility of the same company; in that instance, the foreign facility is the transferee of the export. For imports, the importer may not list its own name as the transferee; however, it may list the name of an affiliated manufacturer, or its own manufacturing facility if it holds a separate registration as a manufacturer, who will process, repackage, or relabel the listed chemical. This is because an importer is permitted to distribute that which it imports, but is not permitted to distribute a chemical which it imported but which has been processed, packaged, labeled, repackaged, or relabeled, subsequent to import. Those activities are defined by the CSA as manufacturing activities (21 U.S.C. 802(15))

and such manufacturing activities may only be carried out by a DEA-registered manufacturer.

DEA recognizes that the exact material imported for a particular customer may not always be distributed to that customer. For example, DEA does not expect an importer to empty a large vat of liquid chemicals based on the order in which DEA Forms 486 were submitted to DEA. DEA would also not expect an importer to segment chemicals stored in its warehouse based on the specific transferee designated on a particular DEA Form 486. So long as all chemicals imported are accounted for in terms of importation and distribution to transferees, this satisfies the requirements of the CMEA.

Return of Chemicals

A related issue raised by two commenters addressed how to handle a return of a product exported to a foreign customer. One of the commenters asked how the supplier (the original exporter), who is now an importer, is to deal with the reporting of the transfer. The commenter noted that in circumstances involving returns, the disposition of the goods may not be decided until they are received back into the supplier's inventories.

DEA Response: In DEA's experience, the return of a product exported to a foreign customer is not a routine occurrence; however, when such instances arise, the return of such products will be treated as imports. Like with all imports, DEA Form 486 must be filed in compliance with DEA regulations. DEA further notes that this issue is not specific to implementation of the CMEA.

Importation for Exportation

A commenter requested clarification about a situation where a United States company imports listed chemicals for the purpose of export. This commenter asked whether it could list a foreign customer as the transferee on an import declaration.

DEA Response: The importation and exportation of the listed chemical are separate transactions conducted under separate DEA registrations. If a United States importer imports a listed chemical for exportation, the United States importer submits to DEA a DEA Form 486 providing information concerning the United States exporter, the United States importer's transferee of the listed chemical. For the United States exporter, the transferee is the foreign importer. The United States exporter submits a separate DEA Form 486 providing information regarding the exportation. Both the importation and exportation of the listed chemical require the subsequent submission of return declarations for each transaction. Note that the requirement to submit separate DEA Forms 486 for the importation and exportation of the listed chemical has not been affected by the CMEA.

Regular Customer Status

One commenter stated that, under the rule, for a customer to obtain regular customer status, they must have an established business relationship for a specified listed chemical or chemicals that has been reported to DEA. The commenter believed that if it has transferred a regulated transaction either once in six months or twice in a year and the transfer has been reported to DEA, no matter what the chemical class, the 15-day advance notice should be able to be waived. If this were not the case, the commenter believed that its delivery time to its customers would be negatively impacted.

DEA Response: The requirement that an importer or exporter must establish a business relationship with a customer on a chemical-by-chemical basis to obtain regular customer status was not changed by the CMEA or the IFR. DEA views not only each customer independently, but also each chemical. There may be cases where a regular customer for one chemical may not be approved as a regular customer for a different chemical.

Another commenter requested that DEA clarify whether the 15-day advance notification requirement applies to the transfer of a listed chemical to regular customers in quantities greater than that indicated on the original form. The commenter believed that it is clear that the notice applies to new customers in this case. The commenter noted that as the transfer of quantities less than that originally reported can be transferred to regular customers without advance notification to DEA, and only needs to be reported on the return declaration, inventory may exist that will allow an importer to transfer a greater quantity than originally indicated to regular customers.

DEA Response: Notification is required for the transfer of a listed chemical to regular customers in quantities greater than that indicated on the original form; however, the notice need not be sent 15 days in advance if the regular customer status has been established. Section 971(d)(1)(C) states that after a notice under subsection (a) or (b) is submitted to the Attorney General, if circumstances change and the importer or exporter ... will be transferring a greater quantity of the chemical than specified in the notice, the importer or exporter shall update the notice to identify ... the most recent quantity ... 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 Attorney

General, except that such 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer.

15-day Advance Notification for Importation of Ephedrine and Pseudoephedrine

One commenter requested clarification regarding the waiver of the 15-day advance notification requirement for regular importers and regular customers with respect to the listed chemicals ephedrine and pseudoephedrine. Section 1313.12 of the IFR states that the 15-day advance notification can be waived for a regulated person who has qualified as a regular importer if the listed chemical is transferred to a regular customer. The commenter noted that in 1995 DEA disqualified regular importer status for the listed chemicals ephedrine and pseudoephedrine; all imports of these chemicals have been subject to the advance 15-day notification requirement. The commenter requested that DEA confirm whether this disqualification would still be in effect after the implementation of the IFR.

DEA Response: The disqualification of regular importer status for ephedrine and pseudoephedrine remains in effect. DEA sent out a separate notice to all DEA-registered importers reiterating the disqualification of regular importer and regular customer status for all importations of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine and drug products containing those three list I chemicals in May 2007. This notice stated that the disqualification from regular importer and regular customer status of the United States importer and its transferees is necessary to enforce the provisions of the CMEA. The CMEA places stringent controls on the importation, manufacture, and retail sale of the list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine because these chemicals—and drug products containing them—are

used domestically to illicitly manufacture methamphetamine and amphetamine, both schedule II controlled substances.

Early Submission of Transferee Information

One commenter requested clarification on how §§ 1313.15 and 1313.08 would apply to future imports. To eliminate the 15-day waiting period on all future imports, the commenter requested that it be able to submit transferee information to allow for the 15-day advance notice to be waived on future imports.

DEA Response: Importers, exporters, brokers, and traders must follow DEA notification requirements for each planned import, export, or international transaction, so that DEA can closely monitor imports, exports, and international transactions of listed chemicals that may be used in the illicit manufacture of controlled substances. The submission of transferee information not affiliated with a specific importation, exportation, or international transaction is not permitted and does not negate any advance notification requirements in effect for the transferee.

DEA Form 486, Import/Export Declaration for List I and List II Chemicals

One commenter supported the change of return paperwork responsibility being transferred from United States Customs and Border Protection to the exporter or importer; however, another commenter requested clarification of this change to the procedures for distributing the form. Another commenter noted that the instructions for DEA Form 486 state that Copy 3 of the export declaration must be returned to DEA, while § 1313.23(c) states that “Copy 3 shall be presented to the U.S. Customs Service.”

Two commenters requested clarification of the requirements for DEA Form 486 when a planned importation or exportation does not take place. Sections 1313.17 and

1313.27 state that an amended DEA Form 486 must be filed, but one commenter suggested that the form should be “withdrawn” and that §§ 1313.17 and 1313.27 should be amended accordingly.

DEA Response: The distribution requirements for DEA Form 486 have not changed and the importer/exporter must send an original copy of DEA Form 486 to the U.S. Customs Service. This has been corrected in the instructions for DEA Form 486. The change is that the U.S. Customs Service no longer has to certify what is being imported or exported. The new return declarations serve as this certification.

Regarding the commenters seeking clarification on DEA Form 486, DEA considers any change to a previously submitted form an “amendment” whether specific information is being amended in the form or the form is being withdrawn. When a planned importation or exportation does not take place, the importer or exporter must submit an amended DEA Form 486, marked “withdrawn” in the fields provided for that purpose on the form.

International Transactions

One commenter asked how the new requirements apply to international transactions, i.e., shipments from a United States-based company’s facilities in a foreign country to a customer within that country or in a different foreign country. Similarly, the commenter asked whether shipping a product from the United States to a foreign entity of the same company would trigger the requirement to submit a DEA Form 486.

DEA Response: The definition of “international transaction” did not change with enactment of the CMEA. The CSA defines an international transaction as follows: “The term ‘international transaction’ means a transaction involving the shipment of a listed

chemical across an international border (other than a United States border) in which a broker or trader located in the United States participates.” 21 U.S.C. 802(42). DEA has never regulated the shipment of listed chemicals from a United States-based company’s foreign facilities to other entities within the country in which the United States-based company’s foreign facility is located. If, however, any foreign entity ships a listed chemical from one foreign country to another foreign country, and that transaction is arranged by a United States broker or trader, the CSA and its implementing regulations apply for purposes of international transactions. As noted previously, shipping a product from the United States to a foreign entity of the same company is an export and must be handled as such.

IV. Summary of the Final Rule

This final rule adopts the September 2006 IFR, with one technical change, and the April 2007 IFR, without change, as amended by the ITDS rule. The technical amendment to the September 2006 IFR involves the definition of the term “retail distributor.” The definition of “retail distributor” in 21 CFR 1300.02(b) is being amended to include ephedrine so that it will mirror the definition of “retail distributor” found in the CSA at 21 U.S.C. 802(49)(A). The September 2006 IFR inadvertently omitted ephedrine from the definition of “retail distributor.”

V. Regulatory Analyses

Administrative Procedure Act

This final rule, with one change to the September 2006 IFR, and without change to the April 2007 IFR, affirms the amendments made by both IFRs that are already in effect. The APA generally requires that agencies, prior to issuing a new rule, publish an

NPRM in the *Federal Register*. The APA also provides, however, that agencies may be excepted from this requirement 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).

As discussed in the September 2006 and April 2007 IFRs, DEA invoked this “good cause” exception to the APA’s notice and comment requirements. For the September 2006 IFR, DEA determined that public notice and comment were impracticable and contrary to the public interest. As for the April 2007 IFR, DEA determined that public notice and comment were unnecessary and impracticable. With the publication of this final rule, DEA is making a technical amendment to the definition of the term “retail distributor.” The definition of “retail distributor” in 21 CFR 1300.02(b), which was set forth in the September 2006 IFR, is being amended to include ephedrine so that it will mirror the definition of “retail distributor” found in the CSA at 21 U.S.C. 802(49)(A). The CMEA set forth this definition in such detail as to be self-implementing. As explained above in section II, DEA inadvertently omitted ephedrine when it set forth the definition of “retail distributor” in the September 2006 IFR. As this definition is already in effect, DEA finds that notice and opportunity for comment for this technical amendment are unnecessary under the APA (5 U.S.C. 553(b)(B)).

Regulatory Flexibility Act

The RFA (5 U.S.C. 601-612) applies to rules that are subject to notice and comment under section 553(b) of the APA. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general NPRM prior to

this final rule for either the September 2006 IFR or the April 2007 IFR. Consequently, the RFA does not apply.

Furthermore, in the September 2006 IFR, although the RFA was determined to not apply, DEA reviewed the potential impacts of the IFR. The IFR was estimated to affect a substantial number of small entities, but DEA did not believe that it would have significant economic impacts on small entities. In the IFR, DEA sought comments where DEA had discretion in the way in which provisions of the CMEA were implemented and regarding impact on manufacturers and distributors. DEA received no information that could be used to quantify any impacts and notes that reports in trade publications have indicated that sales of cold medications, which is where most scheduled listed chemical products are classified, have continued to grow. It seems unlikely, therefore, that regulated sellers have been significantly impacted by the CMEA requirements.

Executive Orders 12866, Regulatory Planning and Review, 13563, Improving Regulation and Regulatory Review, and 13771, Reducing Regulation and Controlling Regulatory Costs

This final rule was developed in accordance with the principles of EO 12866 and 13563. EO 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). EO 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in EO 12866. EO 12866 classifies a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result

in a rule that may: (1) have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

DEA had determined that the September 2006 and April 2007 IFRs were “significant regulatory action[s]” under EO 12866, section 3(f), Regulatory Planning and Review, and accordingly the IFRs were reviewed by OMB. DEA estimated that the statutory changes enacted under the April 2007 IFR imposed minimal costs on United States importers, exporters, brokers, and traders.

As discussed above, this final rule finalizes the IFRs and makes one technical revision to the definition of “retail distributor,” provided in the September 2006 IFR, to mirror the statutory definition of “retail distributor” as set forth by the CMEA. Therefore, this final rule imposes no cost beyond the costs imposed by the IFRs. OMB has determined that this final rule is not a “significant regulatory action” under EO 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by OMB.

This final rule is not a significant regulatory action under EO 12866, it does not impose a cost greater than zero. Therefore, this final rule is not an EO 13771 regulatory action.

Paperwork Reduction Act of 1995

As stated in the September 2006 and April 2007 IFRs, DEA identified information collections and submitted those collection requests to OMB for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995.

The September 2007 IFR updated DEA regulations for the requirements of the CMEA, “Self-certification, Training and Logbooks for Regulated Seller of Scheduled Listed Chemical Products” (OMB control number 1117-0046). The CMEA mandated a number of new information collections and recordkeeping. Regulated sellers are required to train any employee who will be involved in selling scheduled listed chemical products and to document the training. Regulated sellers must also self-certify to DEA that all affected employees have been trained and that the seller is in compliance with all CMEA provisions. Finally, the CMEA mandates that each sale at retail be documented in a written or electronic logbook and that the logbooks be retained for two years.

In the April 2007 IFR, DEA revised the information collected on DEA Form 486: Import/Export Declaration for list I and list II Chemicals [OMB information collection 1117-0023]. Those changes were discussed in the IFR and were necessary for DEA to implement the provisions of the CMEA.

DEA received OMB clearance for the information collections in the two IFRs. In addition, DEA did not receive any comments to the Paperwork Reduction Act aspect of these IFRs and is finalizing that aspect of the IFRs without change.

Executive Order 12988, Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of EO 12988 to eliminate drafting errors and ambiguity, minimizes litigation,

provides a clear legal standard for affected conduct, and promotes simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of EO\ 13132. The final rules does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. The rule does preempt State laws that are less stringent than the statutory requirements. These requirements, however, are mandated under the CMEA and DEA has no authority to alter them or change the preemption. Accordingly, this rulemaking does not have federalism implications warranting the application of EO 13132.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This final rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Unfunded Mandates Reform Act of 1995

DEA has determined pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.*, that this action would not result in any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted for inflation) in any one year. Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Congressional Review Act

This is a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act) (CRA). As explained in the September 2006 and April 2007 IFRs, the April 2007 IFR was not a major rule; however, the September 2006 IFR was a major rule. This final rule finalizes the IFRs and makes one technical revision to the definition of “retail distributor” in the September 2006 IFR to mirror the statutory definition of “retail distributor.” Therefore, this final rule imposes no cost beyond the costs imposed by the IFRs. Pursuant to the CRA, DEA has delivered copies of this rule to both Houses of Congress and to the Comptroller General.

A major rule generally cannot take effect until 60 days after the date on which the rule is published in the *Federal Register*. 5 U.S.C. 801(a)(3). However, the CRA provides that “any rule for which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.” 5 U.S.C. 808. As noted in the above discussion regarding the applicability of the APA, DEA was not required to publish a general NPRM. Therefore, this final rule takes effect as outlined in the “Dates” section of this final rule.

List of Subjects

21 CFR Part 1300

Chemicals, traffic control.

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1310

Drug traffic control, exports, imports, reporting and recordkeeping requirements.

21 CFR Part 1314

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the IFR amending 21 CFR parts 1300 and 1313, which was published at 72 FR 17401 on April 9, 2007, is adopted as a final rule, without change, and the IFR amending 21 CFR parts 1300, 1309, 1310, 1313, and 1314, which was published at 71 FR 56008 on September 26, 2006 (correction at 71 FR 60609 on October 13, 2006), is adopted as a final rule, with the following change, as amended by the final rule published on December 30, 2016 (81 FR 96992), effective January 30, 2017, and delayed on January 30, 2017 (82 FR 8688), until March 21, 2017 (82 FR 8688):

PART 1300--DEFINITIONS

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

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

2. Amend § 1300.02(b) by removing “pseudoephedrine or phenylpropanolamine” from the definition of “Retail distributor” and adding in its place “ephedrine, pseudoephedrine, or phenylpropanolamine”.

Timothy J. Shea,
Acting Administrator.

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