

options that would minimize any significant impact of a rule on small entities. Because the final rule allows the Director of CBER or the Director of CDER, as appropriate, to approve exceptions or alternatives to the regulations for constituent materials, this action increases the flexibility and reduces the regulatory burden for affected entities. Therefore, FDA certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes 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 annually for inflation) in any one year." The current threshold after adjustment for inflation is \$135 million, using the most current (2009) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

The benefit of this regulatory action is its reduction, through greater flexibility in the regulatory requirements, of burdens on the biological products industry. These issues are discussed in greater detail in section I of this document. Industry cost reductions may result in consumers being offered lower prices or wider availability of existing and new biological products; this would have a positive effect on patients' welfare.

Any administrative and paperwork costs associated with this regulatory action are expected to be minimal and widely dispersed among affected entities. Based on FDA experience, we estimate that we would receive a total of approximately three requests annually for an exception or alternative under § 610.15. FDA experience with similar information collection requirements suggests that approximately 1 hour would be required to prepare and submit each such request.

We received comments expressing concern that this rule would generate additional costs in the form of negative public health effects. FDA has considered the potential for adverse consequences, including increased morbidity and mortality, associated with allowing deviations from the constituent materials regulations set forth in § 610.15(a) through (c), and will grant exemptions only in cases where

data indicate that biological products in their exempted forms will be safe, pure, and potent for the conditions for which the applicant is seeking approval. As experience with the October 1981 rule has shown, FDA is able to conduct a constituent materials exemption process in a manner that is consistent with its public health mandate. For all these reasons, we believe the final rule will impose no overall public health cost.

#### *B. Environmental Impact*

The Agency has determined under 21 CFR 25.31(h) that this action is of a type that does not individually or cumulatively have a significant adverse effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### *C. Federalism*

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the final rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### **VI. Paperwork Reduction Act of 1995**

Section 610.15(d) of this final rule contains reporting requirements that were submitted for review and approval to the Director of the Office of Management and Budget (OMB), as required by section 3507(d) of the Paperwork Reduction Act of 1995. The requirements were approved and assigned OMB control number 0910-0666.

#### **List of Subjects in 21 CFR Part 610**

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

#### **PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS**

■ 1. The authority citation for 21 CFR part 610 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

■ 2. Amend § 610.15 by adding paragraph (d) to read as follows:

#### **§ 610.15 Constituent materials.**

\* \* \* \* \*

(d) The Director of the Center for Biologics Evaluation and Research or the Director of the Center for Drug Evaluation and Research may approve an exception or alternative to any requirement in this section. Requests for such exceptions or alternatives must be in writing.

Dated: April 7, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-8885 Filed 4-12-11; 8:45 am]

**BILLING CODE 4160-01-P**

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## **DEPARTMENT OF JUSTICE**

### **Drug Enforcement Administration**

#### **21 CFR Part 1314**

[Docket No. DEA-3471]

RIN 1117-AB30

#### **Self-Certification and Employee Training of Mail-Order Distributors of Scheduled Listed Chemical Products**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Interim final rule with request for comment.

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**SUMMARY:** On October 12, 2010, the President signed the Combat Methamphetamine Enhancement Act of 2010 (MEA). It establishes new requirements for mail-order distributors of scheduled listed chemical products. Mail-order distributors must now self-certify to DEA in order to sell scheduled listed chemical products at retail. Sales at retail are those sales intended for personal use; mail-order distributors that sell scheduled listed chemical products not intended for personal use, e.g., sale to a university, are not affected by the new law. This self-certification must include a statement that the mail-order distributor understands each of the requirements that apply under part 1314 and agrees to comply with these requirements. Additionally, mail-order distributors are now required to train their employees prior to self-certification. DEA is promulgating this rule to incorporate the statutory provisions and make its regulations consistent with the new requirements

and other existing regulations related to self-certification.

**DATES:** *Effective Date:* This rule is effective April 13, 2011.

*Comment Date:* Written comments must be postmarked and electronic comments must be submitted on or before June 13, 2011. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

**ADDRESSES:** To ensure proper handling of comments, please reference "Docket No. DEA-347" on all written and electronic correspondence. Comments may be sent electronically through <http://www.regulations.gov> using the electronic comment form provided on that site. An electronic copy of this document is also available at the <http://www.regulations.gov> Web site. Comments may be sent to DEA by sending an electronic message to [dea.diversion.policy@usdoj.gov](mailto:dea.diversion.policy@usdoj.gov). DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because <http://www.regulations.gov> terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received.

Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/ODL, 8701 Morrisette Drive, Springfield, VA 22152.

All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

**FOR FURTHER INFORMATION CONTACT:** Cathy A. Gallagher, Acting Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152; telephone: (202) 307-7297.

#### **SUPPLEMENTARY INFORMATION:**

##### **Posting of Public Comments**

Please note that all comments received are considered part of the public record and made available for public inspection online at <http://www.regulations.gov> and in the Drug

Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

##### **DEA's Legal Authority**

DEA implements and enforces the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801-971), as amended. DEA publishes the implementing regulations for these statutes in Title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial 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, distribution, importation, and exportation of chemicals that may be used to manufacture controlled substances illegally. 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 October 12, 2010, the President signed the Combat Methamphetamine Enhancement Act of 2010 (MEA) (Pub. L. 111-268). Generally, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires agencies to provide notice of proposed rulemaking and the opportunity for public comment in its regulations implementing an Act of Congress. However, an agency may find good cause to exempt a rule from certain provisions of the APA, 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. DEA is invoking the APA good cause exception and promulgating this rule as an interim final rule rather than a proposed rule because the requirements of the MEA addressed by this rulemaking are self-implementing and changes in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the law. The MEA also specifically states that "[t]he Attorney General may issue regulations on an interim basis as necessary to ensure the implementation of this Act by the effective date." Public Law 111-268, Sec. 6(b). DEA is accepting comments on this rulemaking.

##### **Mail-Order Distributor**

DEA regulations do not specifically define "mail-order distributor." However, part 1314 of the regulations defines "mail-order sale" as "a retail sale of scheduled listed chemical products for personal use where a regulated person uses or attempts to use the U.S. Postal Service or any private or commercial carrier to deliver the product to the customer." 21 CFR 1314.03. Also, mail-order sale "includes purchase orders submitted by phone,

mail, fax, Internet, or any method other than face-to-face transaction.” 21 CFR 1314.03.

The idea of mail-order distributor is further developed later in part 1314, which discusses a “regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration \* \* \*” 21 CFR 1314.100(a). The CSA (21 U.S.C. 830(b)(3)) and its implementing regulations impose recordkeeping and reporting requirements on “[e]ach regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier \* \* \*” 21 CFR 1310.03(c). Such persons are obligated to file monthly reports with DEA. 21 CFR 1310.03(c).

#### **Combat Methamphetamine Enhancement Act of 2010**

The MEA amends the CSA to change the regulations for selling scheduled listed chemical products—nonprescription products that contain ephedrine, pseudoephedrine, and phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. The law requires that each regulated person making sales at retail of a scheduled listed chemical product who is required under Title 21 of the United States Code ((21 U.S.C. 830(b)(3)) to submit monthly reports of sales transactions to the Attorney General (referred to as mail-order distributors) may not sell any scheduled listed chemical product at retail unless such regulated person has submitted to the Attorney General a self-certification. Sales at retail are those sales intended for personal use; mail-order distributors that sell scheduled listed chemical products not intended for personal use, e.g., sale to a university, are not affected by the new law. The requirement of self-certification becomes effective April 10, 2011 (180 days after enactment on October 10, 2010). Mail-order distributors must be self-certified before they can sell scheduled listed chemical products. Such self-certification must be consistent with the criteria established for certifications of regulated sellers—i.e., retail stores and mobile retail vendors—of scheduled listed chemical products.

To that end, and pursuant to the requirements of 21 U.S.C.

830(e)(1)(B)(ii)(II), DEA is requiring that each mail-order distributor must be self-certified at each place of business at which they sell these products at retail. For a mail-order distributor, this would mean that each location that prepares or packages product for distribution to customers, and each location where employees accept payment for such sales, must be self-certified.

Pursuant to the requirements of 21 U.S.C. 830(e)(1)(B)(iii)(I) pertaining to regulated sellers, the self-certification for mail-order distributors is required to take place via the Internet on DEA’s Web site. Self-certification includes a statement that the mail-order distributors understand the requirements and agree to comply with them. MEA also makes it unlawful to negligently fail to self-certify as required under 21 U.S.C. 830, by an amendment to 21 U.S.C. 842(a)(10). Public Law 111–268, Sec. 5. This applies to regulated sellers and mail-order distributors.

The MEA also includes a provision which states that “[t]he Attorney General shall by regulation establish criteria for certifications of mail-order distributors that are consistent with the criteria established for the certifications of regulated sellers under paragraph (1)(B).” 21 U.S.C. 830(e)(2)(C), as amended by Public Law 111–268, Sec. 2. This means that mail-order distributors are now required to train their employees prior to self certification.

#### **Provisions of the Combat Methamphetamine Enhancement Act of 2010**

Prior to MEA, mail-order distributors of scheduled listed chemical products, which covered any sale where the product is shipped using the Postal Service or any private or commercial carrier, did not have to self-certify. They did have to file monthly reports of all sales of scheduled listed chemical products with DEA, and they were required to verify the identity of their customer before shipping scheduled listed chemical products. 21 U.S.C. 830(b)(3) and 830(e)(2)(A).

*Sales of scheduled listed chemical products by mail-order distributors.* MEA requires that on and after April 10, 2011, a mail-order distributor must not sell scheduled listed chemical products at retail unless it has self-certified to DEA, through DEA’s Web site. The self-certification requires the mail-order distributor to confirm the following:

- Its employees who will be engaged in the sale of scheduled listed chemical products have undergone training regarding provisions of the Combat

Methamphetamine Epidemic Act of 2005 (CMEA).

- Records of the training are maintained.
- Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day. For mail-order distributors, sales to individuals do not exceed 7.5 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per 30-day period.

- Nonliquid forms are packaged as required. The mail-order distributor must train its employees and self-certify before either the mail-order distributor or individual employees may sell scheduled listed chemical products. The law governing self-certification of mail-order distributors does not explicitly make such certifications subject to 18 U.S.C. 1001, as is the case for regulated sellers whose sales are limited almost exclusively to face-to-face retail transactions. Compare 21 U.S.C. 830(e)(1)(B) to 830(e)(2)(C). However, a mail-order distributor who knowingly or willfully self-certifies to facts that are not true is subject to fines and imprisonment by virtue of general applicability of 18 U.S.C. 1001. Also, when Congress directed that regulations of the Attorney General establish criteria for the certification of mail-order distributors “that are consistent with the criteria established for the certification of regulated sellers under paragraph (1)(B),” it must have intended that this Federal false statements statute apply.

*Training.* DEA has developed training that it has made available on its Web site (<http://www.deadiversion.usdoj.gov>).

Employers must use the content of this training in the training of their employees who sell scheduled listed chemical products. An employer may include content in addition to DEA’s content, but DEA’s content must be included in the training. For example, a mail-order distributor may elect to incorporate DEA’s content into initial training for new employees.

*Training records.* On and after April 10, 2011, each employee of a mail-order distributor who is responsible for delivering scheduled listed chemical products to purchasers or who deals directly with purchasers by obtaining payment for the scheduled listed chemical products must undergo training and must sign an acknowledgement of training received prior to selling scheduled listed chemical products. This record must be kept in the employee’s personnel file.

*Self-certification.* MEA adds the requirement that mail-order distributors

self-certify with DEA. As noted previously, MEA also makes it unlawful for mail-order distributors to negligently fail to self-certify as required under 21 U.S.C. 830.

On and after April 10, 2011, under the requirements of MEA, mail-order distributors who sell at retail must self-certify to DEA as described above. DEA has established a Web page that will allow mail-order distributors of scheduled listed chemical products to complete the self-certification online and submit it to DEA electronically. A self-certification certificate will immediately be generated by DEA upon receipt of the application. The mail-order distributors will print this self-certification certificate, or if they are unable to print it, DEA will print and mail the certificate to the self-certifier.

**Time for self-certification.** MEA requires that mail-order distributors self-certify by April 10, 2011. When a regulated person files the initial self-certification, the Administration will assign the regulated person to one of twelve groups. The expiration date of the self-certification for all regulated persons in any group will be the last day of the month designated for that group. In assigning a regulated person to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from the date of self-certification. After the initial certification period, the regulated person must update the self-certification annually. It is the responsibility of the mail-order distributor to ensure that they renew the self-certification before it lapses.

**Fee for self-certification.** To comply with the requirement of the CSA that fees be set at a level to ensure the recovery of the full costs of operating the various aspects of the Diversion Control Program, DEA established an annual self-certification fee for certain regulated sellers selling scheduled listed chemical products at retail. The annual self-certification fee for regulated sellers who are not DEA pharmacy registrants is \$21. To make regulations regarding mail-order distributors consistent with those for regulated sellers, the same self-certification fee will apply to any mail-order distributor that is not a DEA-registered pharmacy.

Table 1 summarizes the requirements for mail-order distributors of scheduled listed chemical products that are now in place since the passage of the MEA.

TABLE 1—SUMMARY OF REQUIREMENTS BY TYPE OF SELLER

	Mail-order sellers
Daily sales limit .....	3.6 gm/chemical.
30-day sales limit .....	7.5 gm.
Blister packs .....	Yes.
Storage .....	NA.
Logbook .....	NA.
Customer ID .....	Verify ID.
Train employees .....	Yes.
Self-Certify .....	Yes.
Monthly reports .....	Yes.
Theft and loss reports .....	Yes.

#### Discussion of the Rule

To make the rule easier to follow for regulated sellers and mail-order distributors, DEA previously created part 1314 that includes all requirements related to the sale of scheduled listed chemical products to end users. Subpart A contains requirements that apply to any retail sale. Subpart B applies to regulated sellers (retail distributors and mobile retail vendors). Subpart C applies to retail sales that are shipped by mail or private or commercial carriers, regardless of how those sales are ordered.

In Subpart C, Section 1314.101 is being added to address employee training for mail-order distributors. Section 1314.102 is added to address self-certification for mail-order distributors. Section 1314.103 covers the self-certification fee and the time of payment for this fee. As discussed above, DEA is setting an annual period for renewal of the certification. DEA has developed a page on its Web site that will allow mail-order distributors to complete and submit the self-certification form online and print out a self-certification certificate for their records. The information required will include the name and address of the location, a point of contact, and tax identification number.

#### Regulatory Certifications

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

The Administrative Procedure Act (APA) generally requires that agencies, prior to issuing a new rule, publish a Notice of Proposed Rulemaking in the **Federal Register**. However, the Combat Methamphetamine Enhancement Act specifically states, “[t]he Attorney General may issue regulations on an interim basis as necessary to ensure the implementation of this Act by the effective date.” Public Law 111–268, Sec. 6(b). Additionally, the APA provides that agencies may be exempted from this requirement when “the agency for good cause finds (and incorporates

the finding and a brief statement of reasons therefor 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).

With publication of this interim final rule, DEA is invoking this “good cause” exception to the APA’s notice requirement based on the combination of several factors. The MEA is effective 180 days after its passage. Mail-order distributors selling scheduled listed chemical products at retail must self-certify with DEA in order to continue to sell these products. Based on the effective date and the requirements of the MEA, it is impracticable for DEA to comply with the APA’s notice and comment requirements due to the limited time involved. Were DEA not to publish this interim final rule with Request for Comment, mail-order distributors selling scheduled listed chemical products at retail would not be able to self-certify by the date specified in the law. As a result, these mail-order distributors would be forced to stop selling scheduled listed chemical products, or violate the law by doing so. Thus, DEA also finds it is contrary to the public interest to DEA to comply with the APA’s notice and comment requirements due to the potential disruption of sales of scheduled listed chemical products by mail-order distributors.

In light of these factors, DEA finds that “good cause” exists to issue this interim rule without engaging in traditional notice and comment rulemaking.

#### Regulatory Flexibility Act

The Deputy Assistant Administrator, Office of Diversion Control, hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act (RFA) applies to rules that are subject to notice and comment. DEA has determined, as explained above, that public notice and comment are impracticable and contrary to the public interest. Consequently, the RFA does not apply.

Although the RFA does not apply to this interim final rule, DEA has reviewed the potential impacts. DEA does not believe that it will have a significant economic impact on small entities. Based on reports filed, DEA expects that the rule will affect only 9 firms, two of which are not small based on the Small Business Administration’s size standards. For the seven small firms, the only costs are the \$21 annual fee, the time required to complete the

certification (0.5 hours or about \$20 for a new self-certification application), and cost of training (0.5 hours or about \$10). The cost of compliance for these firms, which appear to have between 5 and 25 employees, not all of whom would need to be trained, is less than \$200 and in most cases, less than \$100. The smallest mail order pharmacies (those with fewer than five employees) have average annual sales of \$1 million. The cost of compliance is, therefore, less than 0.1 percent of sales and would not impose a significant economic burden on any small entity.

#### *Executive Order 12866*

The Deputy Assistant Administrator, Office of Diversion Control, further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 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. However, DEA has reviewed the potential benefits and costs following OMB Circular A–4.

The time for a mail-order distributor to self-certify is estimated at 0.5 hours. Additionally, the time for a mail-order distributor to train employees is estimated at 0.5 hours. The nine affected firms range in size from 5 employees to more than 800. DEA assumes that the smallest firms will train half their employees and the two large firms will train 20 percent, based on the percentage of retail sales persons, order clerks, and order fillers to total employment in the retail mail order sector. The total cost of the rule is estimated to be less than \$2,600. DEA does not expect that the rule will lead any of the firms to discontinue sales of the products because they are already reporting to DEA on these sales. The low cost of compliance is unlikely to discourage firms from selling the products.

*Benefits.* Congress passed the MEA to better track retail sales of scheduled listed chemical products by requiring self-certification of mail-order distributors in addition to regulated sellers (retailers). The MEA also makes it more difficult for regulated sellers and mail-order distributors to obtain scheduled listed chemical products from distributors by prohibiting distributors from selling to them if they have not self-certified. This leaves less opportunity for diversion at the retail level.

Methamphetamine remains the primary drug produced in illicit

laboratories within the United States. The vast majority of these laboratories used pharmaceutical products containing pseudoephedrine, ephedrine, and phenylpropanolamine as the source of precursor material.

*Conclusion.* MEA’s requirements will not impose an annual cost on the economy of \$100 million or more, the standard for an economically significant rule under Executive Order 12866.

#### *Executive Order 13563*

Published on January 18, 2011, Executive Order 13563 supplements and reaffirms the principles established in Executive Order 12866. 76 FR 3821. The new Executive Order emphasizes the importance of public participation and cost-effectiveness within the context of the regulatory process. DEA has carefully considered the requirements of the Executive Order and has concluded that this rule satisfies the applicable requirements. Although the MEA provides authorization to issue rules on an interim basis in order to implement the self-certification requirements of Section 2 of the Act, DEA has requested public comment in order to ensure that its regulatory process maintains a flexible approach and seeks the view of all persons potentially affected by the MEA’s requirements. Further, because this rule contains a 60-day comment period and utilizes regulations.gov regarding its rulemaking docket, it complies with the specific requirements of Section 2(b) of the Executive Order. 76 FR 3821, 3822. Finally, DEA believes its rule to be cost-effective and tailored to impose the least possible burden. There are only 9 mail-order distributors that would be affected by this rule and the cost of implementation is low.

#### *Paperwork Reduction Act of 1995*

To address the new mandates of MEA, DEA is revising an existing information collection “Self-Certification, Training, and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products,” Information Collection 1117–0046. MEA requires mail-order distributors to train any employee who will be involved in selling scheduled listed chemical products and to document the training. Mail-order distributors must also self-certify to DEA that all affected employees have been trained and that the mail-order distributor is in compliance with all provisions of the CMEA.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget for review and

clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The 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 information collection instrument with instructions, should be directed to Cathy A. Gallagher, Acting Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152. Written comments and suggestions from the public and affected agencies concerning the collection of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency’s estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- 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 Information Collection 1117–0046*

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

(2) *Title of the Form/Collection:* Self-certification, Training and Logbooks for Regulated Sellers and Mail-Order Distributors of Scheduled Listed Chemical Products.

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

*Form Number:* DEA Form 597.  
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:* The Controlled Substances Act mandates that regulated sellers of

scheduled listed chemical products maintain a written or electronic logbook of sales. The CSA also requires that regulated sellers and mail-order distributors retain a record of employee training, and complete a self-certification form verifying the training and compliance with CMEA provisions

regarding retail sales of scheduled listed chemical products.

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

As discussed in the previous section, DEA estimates the number of mail-order

distributors to be around 9. The average annual burden hour per respondent is 1.8 hours.

(6) An estimate of the total public burden (in hours) associated with the collection: 16 hours.

The following table presents the burden hour calculations.

TABLE 2—ESTIMATE OF TOTAL BURDEN HOURS

Activity	Unit burden hour	Number of activities	Total burden hours
Training record .....	0.05 hour (3 minutes) .....	410,228	20,511.4
Self-certification (regulated sellers) .....	0.25 hour (15 minutes) .....	64,000	16,000
Self-certification (mail-order distributors) .....	0.5 hours (30 minutes) .....	9	4.5
Transaction record .....	0.033 hour (2 minutes) .....	25,500,000	850,000
Customer time .....	0.033 hour (2 minutes) .....	25,500,000	850,000
<b>Total .....</b>	.....	.....	<b>1,736,515.9</b>

If additional information is required contact: Lynn Murray, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Two Constitution Square, 145 N Street, NE., Suite 2E-502, Washington, DC 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 impose enforcement responsibilities on any State; nor does it diminish the power of any State to enforce its own laws. These requirements, however, are mandated under MEA, and DEA has no authority to alter them or change the preemption. 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 \$126,400,000 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 section 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. It will not cause 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 in 21 CFR Part 1314**

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1314 is amended as follows:

**PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS**

■ 1. The authority citation for part 1314 continues to read as follows:

**Authority:** 21 U.S.C. 802, 830, 842, 871(b), 875, 877, 886a.

■ 2. Section 1314.101 is added to read as follows:

**§ 1314.101 Training of sales personnel.**

Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03(c) of this chapter to submit a report of the sales transaction to the Administration must ensure that its sales of a scheduled listed chemical product at retail are made in accordance with the following:

(a) In the case of individuals who are responsible for preparing and packaging scheduled listed chemical products for delivery to purchasers through the Postal Service or any private or commercial carrier or who deal either directly or indirectly with purchasers by obtaining payments for the products, the regulated person has submitted to the Administration a self-certification that

all such individuals have, in accordance with criteria issued by the Administration, undergone training provided by the regulated person to ensure that the individuals understand the requirements that apply under this part.

(b) The regulated person maintains a copy of each self-certification and all records demonstrating that individuals referred to in paragraph (a) of this section have undergone the training.

■ 3. Section 1314.102 is added to read as follows:

**§ 1314.102 Self-certification.**

(a) A regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must submit to the Administration the self-certification referred to in § 1314.101(a) in order to sell any scheduled listed chemical product. The certification is not effective for purposes of this section unless, in addition to provisions regarding the training of individuals referred to in § 1314.101(a), the certification includes a statement that the regulated person understands each of the requirements that apply in this part and agrees to comply with the requirements.

(b) When a regulated person files the initial self-certification, the Administration will assign the regulated person to one of twelve groups. The expiration date of the self-certification for all regulated persons in any group will be the last day of the month designated for that group. In assigning a regulated person to a group, the Administration may select a group with an expiration date that is not less than 12 months or more than 23 months from

the date of self-certification. After the initial certification period, the regulated person must update the self-certification annually.

(c) The regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Attorney General must provide a separate certification for each place of business at which the regulated person sells scheduled listed chemical products at retail.

■ 4. Section 1314.103 is added to read as follows:

**§ 1314.103 Self-certification fee; time and method of fee payment.**

(a) Each regulated person who makes a sale at retail of a scheduled listed chemical product and is required under § 1310.03 of this chapter to submit a report of the sales transaction to the Administration must pay a fee for each self-certification. For each initial application to self-certify, and for the renewal of each existing self-certification, a regulated seller shall pay a fee of \$21.

(b) The fee for self-certification shall be waived for any person holding a current, DEA registration in good standing as a pharmacy to dispense controlled substances.

(c) A regulated person shall pay the fee at the time of self-certification.

(d) Payment shall be made by credit card.

(e) The self-certification fee is not refundable.

Dated: April 8, 2011.

**Joseph T. Rannazzisi,**  
*Deputy Assistant Administrator, Office of  
Diversion Control.*

[FR Doc. 2011-9016 Filed 4-12-11; 8:45 am]

**BILLING CODE 4410-09-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9515]

RIN 1545-BH20

#### **Guidance Under Section 1502; Amendment of Matching Rule for Certain Gains on Member Stock**

#### **Correction**

In rule document 2011-4846 appearing on pages 11956-11959 in the issue of Friday, March 4, 2011, make the following corrections:

1. On page 11956, in the third column, under the Background heading,

in the third line, “See” should read “See”.

2. On page 11957, in the first column, in the sixth line from the top, “See” should read “See”.

#### **PART 1—[CORRECTED]**

3. On page 11958, in the first column, in the fourth line, in amendatory instruction 3., “Paragraph (c)(7)(iii)” should read “Paragraph (c)(7)(iii)”.

#### **§ 1.1502-13 [Corrected]**

4. On the same page, in § 1.502-13(c)(7)(ii), in Example 16(b), in the third column, in the 36th line, “See” should read “See”.

5. On the same page, in § 1.502-13(c)(7)(ii), in Example 17(b), in the third column, in the fourth line from the bottom, “See” should read “See”.

6. On page 11959, in § 1.502-13(c)(7)(ii), in Example 17(b), in the first column, in the 16th line from the top, “See” should read “See”.

7. On the same page, in § 1.502-13(c)(7)(iii)(B), in the first column, in the third line, “see” should read “see”.

8. On the same page, in § 1.502-13(c)(7)(iii)(B), in the first column, in the seventh line, “see” should read “see”.

#### **§ 1.502-13T [Corrected]**

9. On the same page, in § 1.502-13T(a), in the first column, in the second line, “see” should read “see”.

10. On the same page, in § 1.502-13T(a)(B)(2), in the second column, in the 14th line, “see” should read “see”.

11. On the same page, in § 1.502-13T, in the second column, in paragraph (f)(5)(ii)(B)(3) through (f)(5)(ii)(E), in the second line, “see” should read “see”.

12. On the same page, in § 1.502-13T(a)(F)(2), in the second column, in the third line, “see” should read “see”.

[FR Doc. C1-2011-4846 Filed 4-12-11; 8:45 am]

**BILLING CODE 1505-01-D**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 110

[Docket No. USCG-2008-1082]

RIN 1625-AA01

#### **Anchorage Regulations; Port of New York**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is revising Anchorage Ground No. 19 located east of the Weehawken-Edgewater Federal

Channel on the Hudson River. The revision is necessary to facilitate safe navigation and provide safe and secure anchorages for vessels operating in the area. This action is intended to increase the safety of life and property of both the anchored vessels and those operating in the area as well as to provide for the overall safe and efficient flow of commerce.

**DATES:** This rule is effective May 13, 2011.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2008-1082 and are available online by going to <http://www.regulations.gov>, inserting USCG-2008-1082 in the “Keyword” box, and then clicking “Search.” This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Mr. Jeff Yunker, Coast Guard Sector New York, Waterways Management Division; telephone 718-354-4195, e-mail [Jeff.M.Yunker@uscg.mil](mailto:Jeff.M.Yunker@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

#### **SUPPLEMENTARY INFORMATION:**

##### **Regulatory Information**

On September 18, 2009, we published a notice of proposed rulemaking (NPRM) entitled Anchorage Regulations; Port of New York in the **Federal Register** (74 FR 47906). We received one comment on the NPRM. No public meeting was requested and none was held. On April 28, 2010, we published a supplemental notice of proposed rulemaking (SNPRM) entitled Anchorage Regulations; Port of New York in the **Federal Register** (75 FR 22323). We received one comment on the SNPRM. A public meeting was requested by the New York City Department of Parks and Recreation (NYC Parks) but the Coast Guard determined a public meeting was not necessary in this case. Instead, a meeting with representatives from the NYC Parks, Sandy Hook Pilots Association, and U.S. Army Corps of Engineers New York District was held on August 31, 2010, to discuss their comment in relation to commercial