determines that low flow augmentation projects sponsored by the commission's member states provide sufficient mitigation for agricultural water use to meet the standards set forth in § 806.22, and except as otherwise provided below, agricultural water use projects shall not be subject to the requirements of this paragraph (a)(1). Notwithstanding the foregoing, an agricultural water use project involving a diversion of the waters of the basin shall be subject to such requirements unless the property, or contiguous parcels of property, upon which the agricultural water use project occurs is located at least partially within the basin.

* * * * *

(3) *Diversions.* Except with respect to agricultural water use projects not subject to the requirements of paragraph (a)(1), the projects described below shall require an application to be submitted in accordance with § 806.13, and shall be subject to the standards set forth in § 806.24. The project sponsors of out-of-basin diversions shall also comply with all applicable requirements of this part relating to consumptive uses and withdrawals.

* * * * *

(b) * * *

(3) Transfer of land used primarily for the raising of food, fiber or forage crops, trees, flowers, shrubs, turf products, livestock, or poultry, or for aquaculture, to the extent that, and for so long as, the project's water use continues to be for such agricultural water use purposes.

* * * * *

3. In § 806.6, revise paragraph (b)(3) to read as follows:

§ 806.6 Transfers of approval.

* * * * *

(b) * * *

(3) A project involving the transfer of land used primarily for the raising of food, fiber or forage crops, trees, flowers, shrubs, turf products, livestock or poultry, or for aquaculture, to the extent that, and for so long as, the project's water use continues to be for such agricultural water use purposes.

* * * * *

PART 808—HEARINGS AND ENFORCEMENT ACTIONS

5. Revise the authority citation for part 808 to read as follows:

Authority: Secs. 3.4 (9), 3.5 (5), 3.8, 3.10 and 15.2, Pub. L. 91–575, 84 Stat. 1509 *et seq.*

Dated: September 21, 2007.

Paul O. Swartz,

Executive Director.

[FR Doc. E7–19290 Filed 9–28–07; 8:45 am]

BILLING CODE 7040–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1314

[Docket No. DEA–298P]

RIN 1117–AB13

Combat Methamphetamine Epidemic Act of 2005: Fee for Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products

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

ACTION: Notice of proposed rulemaking.

SUMMARY: As part of its implementation of the Combat Methamphetamine Epidemic Act of 2005 (CMEA), ''regulated sellers'' or persons and entities selling scheduled listed chemical products at retail locations are required to self-certify with DEA relative to certain requirements of the CMEA. The Diversion Control Program is required to recover the full costs of the certification process, under the Controlled Substances Act; as such the DEA is proposing to charge regulated sellers, who are not DEA registrants, a fee for self-certification.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before November 30, 2007.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–298'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also 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. 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.

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 DEA'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 posted online and placed in the DEA's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

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

SUPPLEMENTARY INFORMATION:

Background

DEA implements 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 1399. 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 and distribution 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 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 CMEA amends the CSA to change the regulations for selling nonprescription products that contain ephedrine, pseudoephedrine, phenylpropanolamine, their salts, optical isomers, and salts of optical isomers. DEA implemented the retail provisions of CMEA through an Interim Rule entitled ''Retail Sales of Scheduled Listed Chemical Products; Self-Certification of Regulated Sellers of Scheduled Listed Chemical Products'' published in the **Federal Register** September 26, 2006 (71 FR 56008, corrected at 71 FR 60609, October 13, 2006). In that Interim Rule, DEA extensively discussed its intent to publish this Notice of Proposed Rulemaking, including the various costs to be included in the certification fee and the methodology for calculating fees (see specifically 71 FR 56013–56015, corrected at 71 FR 60609, October 13, 2006).

Section 886a of the Controlled Substances Act (CSA) defines the Diversion Control Program as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration,'' which are further defined as the ''activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals.'' The CSA also states that reimbursements from the Diversion Control Fee Account '' * * * shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities.'' [Pub. L. 108–447 Consolidated Appropriations Act of 2005]

In addition, Section 111(b)(3) of the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395), codified at 21 U.S.C. 886a(3), requires that ''fees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.''

The CMEA of 2005 implements new requirements governing the sale of scheduled listed chemical products, defined as nonprescription drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. As part of these requirements, CMEA requires self-certification for all regulated sellers of scheduled listed chemical products, defining regulated seller to mean a retail distributor (including a pharmacy and mobile retail vendors). The CMEA requires that on and after September 30, 2006, a regulated seller or any of its employees must not sell scheduled listed chemical products unless it has self-certified to DEA, through DEA's Web site. The certification requires the regulated seller to confirm the following:

- Its employees who will be engaged in the sale of scheduled listed chemical products have undergone training regarding provisions of CMEA.
- Records of the training are maintained.
- Daily sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine. (Mobile retail vendors must also confirm that sales to an individual in a 30-day period do not exceed 7.5 grams.)
- Nonliquid forms are packaged as required.
- Scheduled listed chemical products are stored behind the counter or in a locked cabinet.
- A written or electronic logbook containing the required information on sales of these products is maintained.
- The logbook information will be disclosed only to federal, State, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.

The seller must train its employees and certify before either the seller or individual employees may sell scheduled listed chemical products. The certification is subject to the provisions of 18 U.S.C. 1001. A regulated seller who knowingly or willfully certifies to facts that are not true is subject to fines and imprisonment.

The CMEA also exempts retail distributors from registration requirements under the CSA; however, in practice, retail distributors have not previously registered with DEA because they limited their sales to below-threshold quantities and to products sold in blister packs.

Self-Certification Fee

DEA considers the self-certification requirements of the CMEA to fall within the legal definition of control as governed by Section 886a of the CSA (see above). Accordingly, these activities fall under the general operation of the Diversion Control Program and are subject to the requirements of the Appropriations Act of 1993 that mandates that fees charged shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the Diversion Control Program. The self-certification requirements of CMEA fall under these ''various aspects.'' Therefore, DEA is hereby proposing to charge a fee for each self-certification to comply with these statutory requirements to ensure that the full costs of operating the Diversion Control Program are covered by fees as required by law.

The fee for certification will cover all associated costs, including the initial one-time costs of setting up the certification program, web site, and programmatic infrastructure, as well as ongoing costs associated with the provision of certifications, call center support, maintenance of the self-certification system, printing costs for certificates that regulated sellers cannot print, financial management, and other related costs. DEA has established a training program for its employees to implement new requirements of the CMEA, and must establish the infrastructure necessary for the self-

certification program. Required systems include creation of history, renewal cycles, investigative tools, business validation rules, and development and maintenance of the self-certification Web site.

Other DEA activities associated with self-certification and compliance with CMEA include enforcement and judicial proceedings. CMEA gives DEA the authority to prohibit a regulated seller from selling scheduled listed chemical products for certain violations of CMEA. If DEA issues an order to a regulated seller prohibiting that regulated seller from selling scheduled listed chemical products, the regulated seller is entitled to an administrative hearing if the seller files a timely request for a hearing. The costs of these enforcement activities and the subsequent proceedings must be supported through fees pursuant to the above described statutory requirements. However, these costs *are not* reflected in the proposed self-certification fees contained in this rulemaking, as DEA is uncertain of their utilization. Once DEA is able to determine the frequency of use of these tools and their associated costs, these costs will be recovered through fees associated with self-certification as established in future rulemakings.

Regulated sellers submit a certification online via the DEA self-certification web site and will pay a fee by credit card at the time of each self-certification. DEA calculated this fee based on estimated set-up costs in Fiscal Year 2006 ($96,000) and Fiscal Year 2007 operating costs ($1,341,000) totaling $1,437,000, as shown in Table 1 below. The initial systems development and set-up costs will not be repeated in subsequent years. The operational and maintenance costs for Fiscal year 2008 are estimated to be $811,000. Thus, the total amount to be recovered for Fiscal Years 2006 through 2008 is $2,248,000. Total annual costs associated with operating the certification process include staff costs, operational and administrative costs, web hosting, monitoring and maintenance costs (including hardware and software maintenance), and annual inflation adjustments.

To calculate the fee, DEA divided the total costs for Fiscal Years 2006 through 2008 by the anticipated population of affected regulated sellers of 73,000. As of April 10, 2007, 72,258 retailers had self-certified that they were in compliance with the rule.

All costs are shown in the table below for Fiscal Years 2006 through 2008. The self-certification costs reflect the cost per each self-certification per each facility as required by CMEA.

To minimize administrative and collection burdens, it is DEA's policy to round all fees up to the nearest dollar when calculating fees. This is done to ensure that the full cost of the Diversion Control Program is collected as mandated by statute. Therefore, the fee for self-certifications will be $16.00.

TABLE 1.—SELF-CERTIFICATION COSTS AND FEE CALCULATION

Project detail	2006*	2007	2008	Total cost
Planning	$4,000	$37,000	$38,000	$79,000
Design, Development, Deployment	44,000	704,000	72,000	820,000
Call Center, Finance, Mail Room, Printing	36,000	426,000	433,000	895,000
Maintenance	12,000	174,000	177,000	363,000
Enhancements	.....	.....	91,000	91,000
Total	96,000	1,341,000	811,000	2,248,000
Population	.....	73,000	73,000	.....
Cost per certification	.....	19.68	11.11	15.40

*2006 is only 1 month of operations.

PLANNING	5 − FTE, 3% OF THEIR TIME, 1 − DI 5% OF THEIR TIME.
Design, Development, Deployment	10% allocation of effort.
Creation of Registration System*	2 months planning; 6 months development; 2 months testing, Q/A, CM, C&A, deployment.
Operations Support Operations include	Call Center, finance, distribution & printing.

* Registration system includes creation of history, renewal cycles, investigative tools, business validation rules.

TABLE 2.—CALCULATION OF FEE

Cost for FY2006–2008	Number estimated to self-certify	Self-certification and one renewal		Fee for self-certification
$2,248,000	/(73,000	*2)	= $15.40	= $16.00

Methodology Regarding Establishment of Fee

CMEA specifically states that a separate certification is required for each separate location at which scheduled listed chemical products are sold. As such, mobile retail vendors must certify for each location at which sales transactions occur, e.g., a fairground one week, a convention center the next, etc. Similarly, large corporate chains such as chain pharmacies must certify for each individual location at which scheduled listed chemical products are sold. Each location must self-certify for itself. In its Interim Final Rule implementing the retail provisions of the CMEA (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), DEA requested comments on who should be authorized to sign the self-certification for the regulated seller, given that the person must be in a position to confirm all the self-certification requirements listed above and should be authorized to sign documents for the regulated seller.

Additionally, CMEA mandates self-certification for all regulated sellers irrespective of the extent such entities or persons handle scheduled listed chemical products. Accordingly, DEA may not alter the fee structure to account for the extent to which self-certifiers handle these products. An example would include adjusting self-certification fees according to sales volume or size of establishment.

Finally, as mentioned elsewhere in this NPRM, CMEA requires that all persons selling scheduled listed chemical products at retail self-certify to DEA, regardless of whether those persons are registered with DEA to handle controlled substances or List I chemicals.

In a separate Interim Final Rule (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006) implementing the retail provisions of the CMEA, DEA conducted an extensive Economic Impact Analysis in which it estimated approximately 89,000 persons would self-certify to sell scheduled listed chemical products at retail. A brief discussion of this Economic Impact Analysis is found below in this Notice of Proposed Rulemaking. DEA has used this Economic Impact Analysis in the establishment of fees, as well as actual information regarding the number of persons self-certified to sell scheduled listed chemical products, dividing the total costs of self-certification by the estimated number of persons who will self-certify.

CMEA required persons wishing to continue to sell scheduled listed chemical products at retail to self-certify with DEA prior to September 30, 2006. In its Interim Final Rule establishing self-certification and other requirements, DEA established that certification must be renewed annually. However, to spread the population of self-certifiers throughout the year (i.e., to prevent all persons who are self-certified from continuing to renew in the month of September every year), DEA in its Interim Final Rule indicated that it will assign self-certifiers to one of 12 groups. Each group will have an expiration date that will be the last day of a month from 12 to 23 months after the initial filing. The expiration date is contained in each person's or entity's self-certification certificate. After the second certification, regulated sellers will be required to certify annually. Thus, between September 30, 2006, and the end of Fiscal Year 2008 on September 30, 2008, all self-certifiers will have initially self-certified and renewed their certification once, assuming they continue to sell scheduled listed chemical products at retail.

In implementing the self-certification fee, DEA must comply with the CMEA as well as the Consolidated Appropriations Act of 1993 that requires that fees charged shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the Diversion Control Program. In developing the self-certification program and fee structure, DEA considered two options. The first option would be to set an annual fee for certification. However, this methodology would not allow DEA to recover the full costs of the program for certification from fees, as persons selling scheduled listed chemical products will have initially self-certified prior to establishment of the fee. Therefore, DEA decided to establish a fixed fee for Fiscal Years 2006 through 2008, based on the total estimated operating costs of the self-certification process for those Fiscal Years and the anticipated population of regulated sellers that will be required to self-certify. This approach offers a clear fixed fee for this period to entities required to self-certify.

To relieve administrative burdens for the regulated industry and DEA, and for simplicity in accounting and auditing, DEA has rounded these fee calculations up to the nearest dollar. The annual self-certification fee will be clearly defined on the self-certification web site. However, in setting this fee DEA notes that it is based on assumptions about the total number of regulated sellers who will be required to certify. Should the total number of regulated sellers be significantly more or less than 73,000, DEA may adjust the certification fee as appropriate through future rulemakings. Also, as noted above, this fee does not account for certain enforcement and judicial costs associated with self-certification. These costs *are not* reflected in the proposed self-certification fees contained in this rulemaking, as DEA is uncertain of their utilization. Once DEA is able to determine the frequency of use of these tools and their associated costs, these costs will be recovered through fees associated with self-certification as established in future rulemakings. In any case, DEA will not exceed its operating budget as authorized by Congress.

In implementing this fee, DEA also notes that many of the affected regulated sellers are already registered with DEA to dispense controlled substances and therefore already pay a registration/reregistration fee to DEA. The CSA requires that all manufacturers, importers, exporters, distributors and dispensers (e.g., pharmacies) of controlled substances, and List I chemicals obtain an annual registration with DEA. This process also is under the administration of the Diversion Control Program. For example, pharmacies registered with the DEA to distribute controlled substances pay a three-year registration fee of $551 (an annual equivalent of $184). This annual (or three-year) registration fee supports the operations of the Diversion Control Program, including program priorities and field management oversight; coordination of major investigations; drafting and promulgating of regulations relating to the enforcement of the CSA and other legislation; advice and leadership on state legislation/regulation; legal control of drugs and chemicals not previously under federal control; control of imports and exports of licit controlled substances and chemicals; program resource planning and allocation, and investigation, inspection, and cooperative efforts with other law enforcement entities and the regulated industries, among other activities.

DEA considered several options regarding charging fees to registrants and to the new non-registrants regulated pursuant to the Combat Methamphetamine Epidemic Act of 2005. DEA invites comment on its proposed decision regarding the structuring of self-certification fees. DEA considered charging the full costs of the self-certification aspects of the Diversion Control Program only to registrants. However, this would mean that registrants would subsidize the self-certification of non-registrants, and any costs attendant with those self-certifications. Alternatively, DEA could charge only non-registrants for the costs of the self-certification aspects of the Diversion Control Program, as registrants already pay fees to support the Program. However, if DEA were to charge the $2,248,000 cost of the self-certification aspects of the Diversion Control Program to the approximately 18,000 non-registrants, this would result in a renewal fee of $63 per non-registrant self-certifier. As DEA noted previously, both registrants and non-registrants are required to self-certify. Therefore, DEA has elected to spread the costs of self-certification across all registrants, but to waive the self-certification fee for persons registered with DEA.

Additionally, in the course of developing the proposed fee structure, DEA considered an alternative of basing the level of the fee on the size of a business or the volume of the business's sales. Such a fee structure, for example, would allow small businesses below a certain threshold to self-certify without being charged the proposed $16 self-certification fee. In analyzing this option, DEA considered whether the $16 fee would pose a significant hurdle for small businesses and might potentially reduce access to these products if small businesses opted to discontinue carrying scheduled listed

chemical products due to the annual cost of self-certification. Such a fee schedule would need to distinguish between small retailers who sell limited quantities and similarly-sized retailers who, based on their unusual sales volume, may present an increased concern about drug diversion.

However, after careful consideration of this alternative, DEA was concerned that, while it may have the statutory authority to waive a fee under certain circumstances, the agency may not have sufficient statutory authority to collect the kinds of information needed to administer the type of waiver discussed above. DEA would first need to determine an equitable threshold for the size of business or volume of sales below which a waiver would be granted. As DEA does not have historical information regarding size of business or volume of sales, and is not aware of a source of such data, such a determination seems difficult. Further, DEA has concerns about what statute, if any, would provide statutory authority to collect sales data, or other similar information, from persons self-certifying to handle scheduled listed chemical products. If DEA has no statutory authority to collect sales or other information necessary to enforce the fee waiver, then it cannot verify sales or other information on which a waiver would potentially be based, and would have difficulty verifying the veracity of any waiver provisions. For those reasons, DEA has initially proposed not to waive the fee for self-certification based on size of business or volume of sales. DEA invites comment on its interpretation regarding its statutory authority and how to structure self-certification fees in the final rule. In addition, DEA would welcome information about what sort of data might be available to enforce a different fee schedule for small businesses.

That said, DEA notes that while lowering or eliminating the fee depending on the size of a business would reduce the financial burden on small businesses, DEA would have to increase the proposed fee charged to the remaining covered entities to fully fund the self-certification program. In addition to the cost of the proposed self-certification fee, regulated sellers are currently required under existing DEA regulations to maintain a logbook, store covered products behind the counter, and train staff concerning sales and recordkeeping. Because of the costs associated with these existing requirements, DEA currently does not anticipate that the proposed $16 self-certification fee will result in a significant incremental increase in the relative costs of the program for entities carrying covered products, and thus does not currently believe the fee will pose a barrier to access. DEA encourages commenters to provide information on this issue.

While existing registrants are required by the CMEA to self-certify with DEA if selling scheduled listed chemical products, the self-certification fee will be waived upon submission of an active DEA registration number because these registrants already pay an annual fee (or annual fee equivalent) to support the operations of the Diversion Control Program. DEA requests comments on this aspect of this rulemaking.

Regulatory Certifications

Regulatory Flexibility Act

This rulemaking has been drafted in accordance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 601–612). The Administrator of DEA hereby certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

The proposed rule will affect a substantial number of small entities, but will not have a significant economic effect. The fee is minimal—$16 a year. In its Interim Final Rule implementing the retail provisions of the CMEA (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), DEA estimated that the other implementation costs associated with the retail sale of scheduled listed chemical products were also low. DEA estimated that the time required for training sales personnel and filing the self-certification is less than three hours a year. Many of the smallest firms, which are likely to be convenience stores, may limit their sales to single packages of pseudoephedrine where the package contains not more than 60 milligrams. Such sales are exempt from the recordkeeping requirements of the CMEA, which would eliminate the need for logbooks and checking of identification. There will be some cost to move the product behind the counter, but these moves will make open display areas available for other products; the shelf-space costs will, therefore, be offset to some degree. For firms that conduct sales transactions subject to all of the CMEA requirements, most of the cost will derive from the cost of checking identification and completing the logbook entries. That cost will depend on the number of sales. DEA has determined that the smallest stores sold between $20 and $40 a month in these products. This level of sales is the equivalent of five to ten sales per month of packages covered by the logbook requirement or, at the upper limit, about an additional $3.50 per month in transaction costs for the time required to check the identification. For the smallest firms, the annual cost of the rule, with the fee, is likely to be less than $100.

The smallest firms potentially covered are general merchandise stores where the average sales of the smallest firms are $60,000 a year according to the 2002 Retail Trade-Subject Series of the Economic Census. The smallest firms in the other sectors, except for discount department stores and superstores, have annual sales of between $120,000 and $150,000. There are no discount department stores or superstores with annual sales of less than $1 million and $5 million, respectively. The annual fee, therefore, would represent less than 0.03 percent of sales for the smallest store and generally about 0.01 percent of sales. The total cost of the rules for retail sales for the smallest firms is less than 0.2 percent of sales.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). It has been determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Regulated Sellers. As of April 10, 2007, 72,258 retailers had self-certified with DEA. Table 3 presents the number of retailers by sector and indicates whether they have indicated that they are DEA registrants.

TABLE 3.—SECTORS SELLING SCHEDULED LISTED CHEMICAL PRODUCTS

NAICS	Registrants certified	Non-registrants certified
44511 Grocery stores	5,628	913
44611 Pharmacy and drug stores	42,769	1,513

TABLE 3.—SECTORS SELLING SCHEDULED LISTED CHEMICAL PRODUCTS—Continued

NAICS	Registrants certified	Non-registrants certified
452112 Discount Department Stores	2,854	46
45291 Warehouse Clubs and Superstores	2,948	3
Subtotal	54,199	2,475
44512 Convenience stores	12	6,166
44711 Gas Stations with convenience stores	38	8,377
45299 All other general merchandise stores	19	672
Other	173	127
Total	54,441	17,817

Costs/Benefits. As discussed in the previous sections, DEA has estimated costs of $2,248,000 for Fiscal Years 2006 through 2008 for DEA to establish and support the regulated seller self-certification program, which CMEA mandates. As required by law, this cost would be recovered from regulated sellers through a self-certification fee. As noted in the previous section, the proposed fee imposes a minimal burden on regulated sellers. CMEA requires self-certification as a condition of selling these products. The fee will allow DEA to operate a program needed to permit regulated sellers to continue offering scheduled listed chemical products to their customers.

Executive Order 12988

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

Executive Order 13132

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) 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 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1314

Drug traffic control, Reporting and recordkeeping requirements.

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

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

1. The authority citation for part 1314 is proposed to be revised to read as follows:

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

2. Section 1314.42 is proposed to be added to read as follows:

§ 1314.42 Self-certification fee; time and method of fee payment.

(a) A regulated seller shall 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 $16.

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

(c) A regulated seller 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: September 19, 2007.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E7–19215 Filed 9–28–07; 8:45 am]

BILLING CODE 4410–09–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–HQ–OAR–2006–0948; FRL–8475–7]

RIN 2060–AN75

Air Quality: Revision to Definition of Volatile Organic Compounds—Exclusion of Compounds

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to revise EPA's definition of volatile organic compounds (VOCs) for purposes of preparing State implementation plans (SIPs) to attain the national ambient air quality standard for ozone under Title I of the Clean Air Act (Act). This proposed revision would add compounds to the list of compounds excluded from the definition of VOC on the basis that these compounds make a negligible contribution to tropospheric ozone formation. The compounds under consideration are propylene carbonate and dimethyl carbonate. The EPA is inviting comment on an alternative evaluation criteria for exempting one of these compounds (propylene carbonate), methods for tracking changes in the use and emissions of both of these compounds and their potential substitutes, and the potential for health risks that may result from this action.

DATES: Comments must be received on or before October 31, 2007.

Public Hearing: If anyone contacts us requesting to speak at a public hearing on or before October 16, 2007, we will hold a public hearing. Additional