Shippers did not provide sufficient justification for the Commission to further modify the requirements of FERC Form Nos. 6 and 6–Q.

9. The Commission recognizes that FERC Form No. 6 contains only enough information for a threshold determination of whether the existing rates are just and reasonable. However, the Commission concludes that FERC Form Nos. 6 and 6–Q continue to provide sufficient information to allow shippers to file a complaint requesting a determination of the justness and reasonableness of a pipeline's rates. Accordingly, the Commission concludes that no changes to FERC Form Nos. 6 and 6–Q are warranted at this time, and the Commission terminates Docket No. RM07–9–000.

The Commission Orders

Docket No. RM07–9–000 is hereby terminated, as discussed in the body of this order.

By the Commission.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–30621 Filed 12–24–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0039]

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Triamcinolone Cream

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Modern Veterinary Therapeutics, LLC. The ANADA provides for veterinary prescription use of triamcinolone cream on dogs for topical treatment of allergic dermatitis and summer eczema.

DATES: This rule is effective December 29, 2008.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Modern Veterinary Therapeutics, LLC, 1550 Madruga Ave., suite 329, Coral Gables, FL 33146, filed ANADA 200–459 that provides for veterinary prescription use of VETAZINE (triamcinolone acetonide) Cream on dogs for topical treatment of allergic dermatitis and summer eczema. Modern Veterinary Therapeutics, LLC's VETAZINE Cream is approved as a generic copy of VETALOG Cream, sponsored by Fort Dodge Animal Health, A Division of Wyeth Holdings Corp., under NADA 46–146. The ANADA is approved as of November 13, 2008, and the regulations are amended in § 524.2481 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. In § 524.2481, revise paragraphs (b), (c)(2), and (c)(3) to read as follows:

§ 524.2481 Triamcinolone cream.

* * * * *

(b) *Sponsor*. See Nos. 015914, 053501, and 054925 in § 510.600(c) of this chapter.

(c) * * *

(2) *Indications for use*. For topical treatment of allergic dermatitis and summer eczema.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: December 18, 2008.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. E8–30694 Filed 12–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1314

[Docket No. DEA–298F]

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: Final rule.

SUMMARY: To comply with the requirement of the Controlled Substances Act 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, this Final Rule establishes an annual self-certification fee for certain ''regulated sellers,'' that is, persons and entities selling scheduled listed chemical products at retail locations who are required to self-certify with DEA relative to compliance with certain requirements of the Combat Methamphetamine Epidemic Act of 2005 (CMEA). This Final Rule establishes the annual self-certification fee for regulated sellers who are not DEA pharmacy registrants.

DATES: *Effective Date:* February 1, 2009. The new fee will be in effect for all new applications electronically sent on or after the effective date and for all renewal applications electronically sent on or after the effective date.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152; Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Background and Statutory Authority

The Drug Enforcement Administration (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 Final 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 Final Rule, DEA extensively discussed its intent to issue a rulemaking to establish the certification fee for regulated sellers of scheduled listed chemical products and the methodology for calculating fees (see specifically 71 FR 56013–56015, September 26, 2006; corrected at 71 FR 60609, October 13, 2006). To this end, DEA published a Notice of Proposed Rulemaking proposing self-certification fees for regulated sellers selling scheduled listed chemical products at retail on October 1, 2007 (72 FR 55712). This rulemaking finalizes that Notice of Proposed Rulemaking.

Section 886a of the 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.''

CMEA 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 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 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.
- Without regard to the number of transactions, a regulated seller may not in a single calendar day sell any purchaser more than 3.6 grams of ephedrine base, 3.6 grams of pseudoephedrine base, or 3.6 grams of phenylpropanolamine base in scheduled listed chemical products. (A mobile retail vendor may not in any 30-day period sell an individual purchaser more than 7.5 grams ephedrine base, 7.5 grams pseudoephedrine base, or 7.5 grams phenylpropanolamine base.)
- 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 scheduled listed chemical 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 regulated 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.

On October 1, 2007, DEA published a Notice of Proposed Rulemaking outlining the calculations for the proposed fee and compliance requirements for the self-certification fee (72 FR 55712).

II. Comments Received

Following publication of the October 1, 2007, Notice of Proposed Rulemaking, DEA received seven comments. Comments generally supported DEA's proposed certification fee approach and methodology and DEA's exemption of regulated sellers of scheduled listed chemical products who already maintain an active DEA registration as a pharmacy to dispense controlled substances. Five of the comments were from pharmaceutical associations; one comment was from a large chain pharmacy, and one comment was from an individual.

Fee and fee structure: Commenters generally supported DEA's proposed fee of $16 to self-certify and supported DEA's calculation of this fee based on the overall program costs. One commenter noted that this methodology

distributes the program costs to all sellers. Several commenters noted that the fee did not represent a burdensome amount. DEA agrees that the $16 proposed fee, finalized at $21, will not constitute a financial burden on regulated sellers and adds that businesses for which the self-certification fee would have been a barrier have stopped carrying the products due to other compliance costs associated with CMEA. Several commenters specifically noted their opposition to calculating the self-certification fee based on business size or overall volume of sales. Commenters questioned whether DEA had the statutory authority to collect such information, and noted that such collection would be administratively intensive, thereby further increasing fees charged. DEA also notes that it does not have the statutory authority or resources to be investigating these business details of regulated sellers. One commenter, who noted that it did not believe that DEA has this statutory authority to collect such information, also added that even if DEA had the statutory authority to collect the type of information necessary to enable this type of fee structure, it believed that the administrative burden of collecting this information would force an increase in self-certification fees to cover such administrative costs. The commenter therefore opposed this methodology on both grounds.

Fee exemption for registrants registered to dispense controlled substances: All seven commenters supported the fee exemption for regulated sellers who already maintain an annual registration to dispense controlled substances, i.e., a pharmacy registration. In the Notice of Proposed Rulemaking, DEA described the fee exemption for this group of registrants who already pay an annual fee or annual fee equivalent to support the operations of the Diversion Control Program.

Harmonization of registration and self-certification: Related to these comments, five commenters requested that DEA harmonize the self-certification and annual registration/reregistration process. Currently the majority of DEA registrants—practitioners (which includes pharmacies)—renew their registration with DEA every three years and pay a three-year fee to support the operations of the Diversion Control Program. DEA periodically recalculates the fee schedule for all registrants to ensure compliance with the statutory requirement that the full costs of operating the various aspects of the Diversion Control Program are supported through registration fees. Because self-certification occurs annually and registration of practitioners, including pharmacies, occurs every three years, there is no way to combine these two processes. That is, because the time frames are not concurrent, DEA cannot harmonize the renewal of self-certification and registration/reregistration for pharmacies at this time. DEA has made every effort to provide as much harmonization as possible by permitting those pharmacies who register with DEA through the chain registration process to also self-certify using that process. Furthermore, when requested by individual registrants, DEA has endeavored to allow the self-certification to expire in the same month, but not necessarily the same year, as the DEA registration.

DEA is considering whether to revise the time period for registration of practitioners (for example, requiring registration on an annual basis). If DEA pursues this course of action, it will publish a separate rulemaking requesting public comment on such a change.

Reminder of self-certification requirement: One commenter suggested that DEA develop an annual outreach program to remind regulated sellers of their annual self-certification requirement. Because self-certification is a certification by the regulated seller of compliance with the requirements of CMEA, DEA believes that it is the responsibility of the regulated seller to obtain and maintain their self-certification in good standing. Congress indicated in CMEA that self-certification is the responsibility of the regulated seller and strictly limited DEA involvement in the self-certification process (21 U.S.C. 830(e)(1)(B)(iii)).

Signature of self-certification: In the Notice of Proposed Rulemaking DEA noted that it had previously requested comments regarding 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. Two commenters responded to the request. Both commenters suggested that the manager of the regulated seller be authorized to sign the self-certification for the regulated seller. DEA appreciates these responses and will address this specific issue in a separate rulemaking, as this Final Rule is intended only to address the self-certification fee and not other aspects of the self-certification process.

Waiver of self-certification fee for distributors of List I chemicals: One commenter requested that DEA consider waiving the self-certification fee for entities that own both distributors of List I chemicals and retailers of controlled substances (e.g., non-pharmacy retailers). DEA proposed the waiver of the self-certification fee for retail pharmacies who already maintain a registration with DEA because the retail sale of scheduled listed chemical products is essentially the same activity as dispensing (that is, sale at retail) of controlled substances. Thus it makes sense to exempt this category of registered regulated sellers because the activities are in fact similar. However, the distribution of List I chemicals at the non-retail level is not a similar activity to retail dispensing or sales to individual purchasers. DEA also notes that self-certification is only required for retail (not wholesale) distributors of scheduled listed chemical products. If, as the commenter claimed, there are entities that distribute List I chemical products and sell such products at the retail level, then even prior to enactment of CMEA such entities would have been required to maintain two separate registrations—one as a retail distributor and one as a non-retail distributor. Accordingly, the self-certification fee is not waived for non-retail distributors of List I chemicals.

Enforcement costs: Finally, one commenter observed that the calculation of the self-certification fee in the Notice of Proposed Rulemaking did not include any enforcement costs, adding that this omission was ''astonishingly optimistic'' and suggesting that DEA include a small amount of anticipated enforcement costs to the overall fee calculation, and that doing so ''still would not make it burdensome.'' As DEA noted in the Notice of Proposed Rulemaking, the self-certification fee included in this Final Rule does not include DEA activities associated with 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. Following such an order, the affected regulated seller is entitled to an administrative hearing (if requested in a timely manner). While the costs of these enforcement activities and the subsequent proceedings must be supported through fees pursuant to the statutory requirements previously described above, because DEA is uncertain of the resources required and the likely costs of these activities, these costs are not reflected in the self-certification fee contained in this Final Rule. 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.

III. Self-Certification Fee

DEA considers the self-certification requirements of the CMEA to fall within the legal definition of controlled substance and chemical diversion control activities 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, by this Final Rule DEA will charge a fee for each self-certification to comply with these statutory requirements and ensure that the full costs of operating the Diversion Control Program are covered by fees as required by law.

The fee for certification will be applied to 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 program to train its employees to provide information regarding, and accept, certifications and must establish the infrastructure necessary for the program. Required systems include creation of history, renewal cycles, investigative tools, business validation rules, and development and maintenance of the self-certification Web site.

As discussed previously, 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 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 certification. DEA calculated this fee based on estimated set-up costs in Fiscal Year 2006 ($93,369) and Fiscal Years 2007 and 2008 operating and maintenance costs ($1,338,484 and $808,643, respectively) totaling $2,240,496, as shown in Table 1 below. The initial systems development and set-up costs will not be repeated in subsequent years. Thus, the total amount to be recovered for Fiscal Years 2006 through 2008 is $2,240,496. 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 55,000. As of October 27, 2008, 53,989 retailers had self-certified that they were in compliance with the rule. In making the final fee calculation, DEA doubled the number of self-certified sellers from 55,000 to 110,000 to reflect one self-certification and one renewal by each person during Fiscal Years 2006–2008, the time period for which fees were calculated. DEA notes that it has adjusted the population of regulated sellers to accurately characterize the current number of persons self-certified with DEA. This adjustment has resulted in a higher cost per self-certified location than DEA proposed in the Notice of Proposed Rulemaking. 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 $21.00.

TABLE 1—SELF-CERTIFICATION COSTS AND FEE CALCULATION

Project detail	2006*	2007	2008	Total cost
Planning (1)	$3,029	$36,343	$37,002	$76,373
Design, Development, Deployment (2)	$43,512	$703,863	$71,662	$819,037
Call Center, Finance, Mail Room, Printing (3)	$35,423	$425,075	$432,777	$893,275
Maintenance (4)	$11,405	$173,203	$176,341	$360,949
Enhancements (5)	.....	.....	$90,861	$90,861
Total	$93,369	$1,338,484	$808,643	$2,240,496
Population	.....	55,000	55,000	.....
Cost per certification (= total cost/population)	.....	$26.04	$14.71	$20.38

*2006 is only one month of operations.
Planning*
Design, Development, Deployment.
Creation of self-certification system**
Operation support includes:
5 FTE, 3% of their time; 1 D/I 5% of their time.
10% allocation of effort, 2 months planning; 6 months development; 2 months testing, Q/A, CM, C&A, deployment.
Call center, finance, distribution and printing operations.
** Self-certification system includes creation of history, renewal cycles, investigative tools, business validation rules.

TABLE 2—CALCULATION OF FEE

Cost for FY2006–2008	No. estimated to self-certify	Self-certification and one renewal		Fee for self-certification
$2,241,000	/(55,000	* 2)	= $20.38	= $21.00

All regulated sellers will pay the $21 fee upon annual self-certification to the DEA with the exception of those regulated sellers who already maintain an active registration with DEA to dispense controlled substances, *i.e.*, pharmacy registrants. In making this exception, as described in further detail in the Notice of Proposed Rulemaking (72 FR 55712), DEA notes that many of the regulated sellers affected by the self-certification requirement already are 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 DEA to dispense 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.

While these 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 pharmacy registration number in good standing because these registrants already pay an annual fee (or annual fee equivalent) to support the operations of the Diversion Control Program.

DEA remains uncertain of the anticipated costs associated with enforcement activities related to self-certification. Investigative and other activities designed to ascertain and ensure compliance with CMEA will require funding in excess of one-time set-up and maintenance expenses. DEA anticipates publishing a Notice of Proposed Rulemaking to revise the fee for self-certification in the near future. That rule will address costs related to enforcement activities, as well as other expenses related to self-certification of regulated sellers of scheduled listed chemical products. As with all fees collected by DEA, fees collected beyond Fiscal Year 2008, the projected end of the three-year cycle discussed above, will ensure recovery of the full costs of the various aspects of the Diversion Control Program as mandated by statute (21 U.S.C. 886a). Those various aspects of the Diversion Control Program could include, among other things, costs of enforcement activities associated with self-certification.

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 separate location at which scheduled listed chemical products are sold. Each location must self-certify for itself, although DEA has established a process for the self-certification of pharmacies participating in DEA's chain pharmacy renewal program.

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, for example adjusting self-certification fees according to sales volume or size of establishment. DEA notes, as discussed above, that all commenters supported this position.

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

In its Interim Final Rule establishing self-certification and other requirements (71 FR 56008, September 26, 2006; corrected at 71 FR 60609, October 13, 2006), 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 regulated seller'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. Payment of the self-certification fee will be completed at the same time as self-certification.

Regulatory Certifications

Regulatory Flexibility Act

The Acting Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. As discussed previously, DEA has adjusted the population of regulated sellers to accurately characterize the current number of persons self-certified with DEA. This adjustment has resulted in a higher cost per self-certified location ($21) than DEA proposed in the Notice of Proposed Rulemaking ($16).

The Final Rule will affect a substantial number of small entities, but

will not have a significant economic impact. The fee is minimal—$21 a year. The smallest firms potentially covered are general merchandise stores (NAICS 45299) 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 (NAICS 44511 (grocery stores), 44512 (convenience stores), 44611 (drug stores), 44711 (gas stations with convenience stores)), except for discount department stores (NAICS 452112) and superstores (NAICS 45291), 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 0.05 percent of sales for the smallest store and generally about 0.01 percent of sales, which does not impose a significant economic impact.

Executive Order 12866

The Acting 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 October 27, 2008, 53,989 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	3,781	850
44611 Pharmacy and drug stores	27,678	500
452112 Discount Department Stores	1,777	25
45291 Warehouse Clubs and Superstores	4,373	6
Subtotal	37,609	1,381
44512 Convenience stores	3	5,499
44711 Gas Stations with convenience stores	0	9,020
45299 All other general merchandise stores	9	214
Other	42	212
Total	37,663	16,326

Costs/Benefits. As discussed in the previous sections, DEA has estimated costs of $2,240,496 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 will be recovered from regulated sellers through a self-certification fee. As noted in the previous section, the 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 million 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 amended as follows:

PART 1314—RETAIL SALE OF SCHEDULED LISTED CHEMICAL PRODUCTS

■ 1. The authority citation for Part 1314 is revised to read as follows:

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

■ 2. Section 1314.42 is added to read as follows:

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

(a) A regulated seller 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 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.

December 18, 2008.

Michele M. Leonhart,

Acting Administrator.

[FR Doc. E8–30800 Filed 12–24–08; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 180

Consolidated HUD Hearing Procedures for Civil Rights Matters

CFR Correction

In title 24 of the Code of Federal Regulations, parts 0 to 199, revised as of April 1, 2008, on pages 733 and 734, in § 180.670, remove paragraphs (b)(3)(iii)(A) through (b)(3)(iii)(C).

[FR Doc. E8–30942 Filed 12–24–08; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9442]

RIN 1545–BA11

Consolidated Returns; Intercompany Obligations

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 1502 of the Internal Revenue Code (Code). The regulations provide guidance regarding the treatment of transactions involving obligations between members of a consolidated group. These final regulations will affect affiliated groups of corporations filing consolidated returns.

DATES: *Effective Date:* These regulations are effective on *December 24, 2008*.

Applicability Date: For dates of applicability, see §§ 1.1502–13(g)(8) and 1.1502–28(d).

FOR FURTHER INFORMATION CONTACT: Frances Kelly, (202) 622–7770 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On September 28, 2007, the IRS and the Treasury Department published a notice of proposed rulemaking (REG–107592–00) in the **Federal Register** (72 FR 55139) (the 2007 Proposed Regulations) which proposed to amend § 1.1502–13(g) (regarding the treatment of transactions involving obligations between members of a consolidated group) and to add § 1.1502–13(e)(2)(ii)(C) (regarding the treatment of certain transactions involving the provision of insurance between members of a consolidated group). The 2007 Proposed Regulations replaced an earlier proposal (REG–105964–98) [63 FR 70354], published in the **Federal Register** on December 21, 1998, which was withdrawn.

On February 25, 2008, the IRS and the Treasury Department published a notice (Announcement 2008–25) in the **Federal Register** (73 FR 9972) withdrawing the portion of the 2007 Proposed Regulations relating to the treatment of intercompany insurance transactions. No public hearing regarding the remaining portion of the 2007 Proposed Regulations was requested or held. However, written, electronic, and oral comments were received. After consideration of all of the comments, the 2007 Proposed Regulations are adopted as revised by this Treasury decision. The principal comments and changes are discussed in this preamble.

Explanation of Provisions

Former Regulations Under § 1.1502–13(g) (the Former Regulations)

An intercompany obligation is generally defined as an obligation between members of a consolidated group, but only for the period during which both the creditor and debtor are members of the group. The Former Regulations under § 1.1502–13(g) (the 1995 regulations and the 1998 proposed regulations, as in effect before these final regulations), prescribe rules relating to the treatment of transactions involving such obligations, and apply generally to three broad categories of transactions; transactions in which an obligation between a group member and a nonmember becomes an intercompany obligation (inbound transactions), transactions in which an intercompany obligation ceases to be an intercompany obligation (outbound transactions), and transactions in which an intercompany obligation is assigned or extinguished within the consolidated group (intragroup transactions).

For all three types of transactions, the intercompany obligation is treated as satisfied and, if it remains outstanding, reissued as a new obligation (the deemed satisfaction-reissuance model).

Significant Changes Made by the 2007 Proposed Regulations

The 2007 Proposed Regulations make several significant changes to the Former Regulations, principally with respect to intragroup and outbound transactions.

First, the 2007 Proposed Regulations simplify the mechanics of the deemed satisfaction-reissuance model by separating the deemed transactions from the actual transaction. In general, the new model deems the following sequence of events to occur immediately before, and independently of, the actual transaction: (i) the debtor is deemed to satisfy the obligation for a cash amount equal to the obligation's fair market value, and (ii) the debtor is deemed to immediately reissue the obligation to the original creditor for that same cash amount. The parties are then treated as engaging in the actual transaction but with the new obligation.

Second, the 2007 Proposed Regulations provide that for transactions where it is appropriate to require a deemed satisfaction and reissuance, the intercompany obligation generally should be deemed satisfied and reissued for its fair market value (rather than issue price determined under the original issue discount principles of sections 1273 and 1274).

Third, the 2007 Proposed Regulations narrow the scope of intragroup and outbound transactions that trigger the deemed satisfaction-reissuance model by providing a number of exceptions to its application. A deemed satisfaction and reissuance generally is not required for these excepted transactions either because it is not necessary to apply the deemed satisfaction-reissuance model to carry out the purposes of § 1.1502–13(g) or because the burdens associated with valuing the obligation or applying the mechanics of the deemed satisfaction-reissuance model outweigh the benefits achieved by its application.

Finally, the 2007 Proposed Regulations include two anti-abuse rules, the ''material tax benefit rule'' and the ''off-market issuance rule,'' which are intended to prevent distortions of consolidated taxable income resulting from the shifting of built-in items from intercompany obligations, or from the issuance of obligations at a materially off-market rate of interest through the manipulation of a member's tax attributes or stock basis. These rules are aimed at intragroup transactions otherwise excepted from the deemed satisfaction-reissuance model (to ensure that the exceptions cannot be used to distort consolidated taxable income