Supporting Statement for Paperwork Reduction Act Submissions
21 CFR Part 1305
U.S. Official Order Forms for Schedule I and II Controlled Substances (Accountable Forms), Order Form Requisition

This Information Collection Request (ICR) covers the requirements for ordering Schedule I and II controlled substances under 21 CFR part 1305. This ICR revises ICR 1117-0010.

Part A. Justification

1. Necessity of Information:

The Controlled Substances Act (CSA) (21 U.S.C. 801 et seq.) requires the Drug Enforcement Administration to establish a closed system of control for substances that have a potential for abuse. Section 828 of the CSA mandates that DEA provide a form to registrants to be used to purchase Schedule I and II controlled substances. No person may distribute a Schedule I and II controlled substance except in response to an order issued on the DEA-provided form. DEA's regulations implementing section 828 are in 21 CFR part 1305.

At the registrant's request, DEA provides registrants with books of Form 222, preprinted with the registrant's name, address, and DEA registration number, for ordering Schedule I and II controlled substances. The forms must be signed by either the person who signed the most recent registration or reregistration application or someone granted power of attorney by that person. The purchaser retains one copy and sends the other two copies to the supplier. The supplier annotates the two copies, retains one, and forwards the second to DEA. The purchaser is required to annotate its copy when the order is received. As mandated by 21 U.S.C. 828(c), the purchaser and supplier must retain their copies for two years. DEA provides registrants with Form 222a to requisition additional order forms, but allows registrants to order them online as well.

In 2005, DEA adopted rules to allow registrants to issue orders for Schedule I and II controlled substances electronically provided that the electronic order is signed using a digital certificate issued by the DEA Certification Authority. (DEA refers to this electronic order system as "CSOS": Controlled Substances Ordering System.) Records of electronic orders are kept electronically. Reports to DEA are also electronic.

2. Needs and Uses:

Form DEA-222 or its electronic equivalent provides the Drug Enforcement Administration with control over the manufacture, distribution, and dispensing of Schedule I and II controlled substances. The order also serves as an accountable document within a closed recordkeeping system, which must be maintained by each registrant. The preprinted form or a DEA-issued digital certificate ensures that only registrants can order Schedule I and II substances and that these orders are delivered to the registrant at the registered location. The existence of multiple

paper copies of the order, held by different parties, provides a check against any tampering with the document, as does the digital signature, which will indicate whether the file has been altered after signing. DEA uses the information on the orders to investigate possible diversion.

3. Efforts to Minimize Burden:

DEA allows, but does not require, registrants to issue electronic orders. Once a registrant or someone authorized to sign orders for the registrant obtains a digital certificate issued from the DEA Certification Authority, the registrant may issue orders for Schedule I and II controlled substances and maintain records of those orders electronically.

4. Efforts to Identify Duplication:

For registrants who choose not to send orders electronically using digital certificates, orders issued on a Form 222 may duplicate orders that purchasers issue electronically to their suppliers. When registrants switch to electronic orders, no duplication exists.

DEA requires that suppliers submit copies of filled Forms 222 to DEA monthly. DEA requires that suppliers submit either copies of electronic orders or a report on filled electronic orders to DEA every second business day. When suppliers elect to submit reports on electronic orders, the report is in the format used to submit reports quarterly to DEA's Automation of Reports and Consolidated Orders System (ARCOS), with four additional data elements to cover data on the Form 222 that are not collected under ARCOS. The reports serve as a substitute for ARCOS reporting on Schedule I and II substances.

5. Methods to Minimize Burden on Small Businesses:

This information collection does not have a significant impact on small businesses. The move to electronic orders will reduce the burden on small entities.

6. Consequences of Less Frequent Collection:

The frequency of orders and requisitions is driven by the needs of purchasers, not by the regulation. Title 21 U.S.C. 828 requires that DEA provide the order forms and that registrants maintain copies for a period of two years. DEA does not have the authority to reduce the period of recordkeeping.

7. Special Circumstances Influencing Collection:

DEA requires suppliers to submit copies of annotated paper orders to DEA monthly. The supplier receives two copies of the order from the purchaser, annotates them, retains one and sends the second copy to DEA. This submission is necessary to provide DEA with a record of orders so that potential diversion can be identified and investigated in a timely manner. With electronic orders, DEA requires electronic submission of either the orders or a report on the orders every second business day. With the Form 222 system, DEA knows how many forms are printed and who holds them. With the electronic system, DEA has no information on orders being issued. DEA determined that waiting a month to collect information on electronic orders was contrary to the CSA mandate for a closed system of control. Because the reports are generated automatically and transmitted electronically, the increased reporting does not impose a burden.

Other special circumstances are not applicable to this information collection.

8. Reasons for Inconsistencies with 5 CFR 1320.6:

DEA published the Notice of Proposed Rulemaking regarding the electronic ordering of controlled substances June 27, 2003 (68 FR 38558) and a Final Rule on April 1, 2005 (70 FR 16901), and received no comments specific to the information collection discussed in the rule documents.

9. Payment or Gift to Claimants:

There are no such payments or gifts to respondents.

10. Assurance of Confidentiality:

No information on individuals is collected.

11. Justification for Sensitive Questions:

Questions of a sensitive nature are not included in reporting requirements.

12. Estimate of Hour Burden:

Regulated Entities

Table 1 shows the number of registrants, by business activity, that ordered Schedule I or II substances in 2007. These numbers are used as the basis for all other calculations. Registrants are allowed to delegate authority to sign orders through a formal power of attorney (POA).

The number of POAs is estimated based on information from industry on the number of people who hold POA at different types of facilities. Four chain pharmacies handle all orders for their approximately 10,580 registered locations centrally. Each of those four companies is assumed to have six people with POA; all other pharmacies are assumed to have two POA per pharmacy.

Manufacturers and distributors are generally both purchasers and suppliers. Importers may only act as suppliers. All other listed registrants are purchasers. Only suppliers file reports with DEA.

Table 1: Number of Registrants

Registrant Type	Number of Registrants	Number of POAs
Manufacturers	220	1,320
Distributors	335	2,010
Importers	2	N/A
Hospitals/Clinics	10,120	20,240
Pharmacies	63,085	105,036
Teaching Institutions	36	72
Exporters	47	47
Narcotic Treatment Programs, Researchers, Chemical Analysts	2,212	2,212
Practitioners	20,223	N/A
TOTAL	**96,280**	**130,890**

Activities

This ICR includes details on activities for both paper and electronic orders because DEA registrants are adopting electronic orders over time. At the end of 2007, 16,692 of the 96,280 registrants issuing orders had obtained CSOS certificates. Based on unique order numbers processed through ARCOS, about 4.2 million orders were processed on Form 222s and 28,520 were processed electronically. The paper orders represented about 16.8 million transactions (or about 4 per order); the electronic orders represented about 3.1 million transactions or slightly more than 100 per order.

Paper Forms

Registrants who order Schedule I and II controlled substances on paper (purchasers) must do the following:

- Complete Form 222a to requisition books of Form 222 or order them through DEA's web site.
- Fill out a Form 222 for each order for each supplier. A form may contain orders for up to 10 Schedule I and II substances, but no orders for other substances.
- Send copies 2 and 3 of the Form 222 to the supplier.
- Log and track the form.
- Annotate copy 1 when the filled order is received.
- File and maintain the copy for two years.
- Create a POA letter for each POA, signed by the registrant, the POA, and two witnesses.

The supplier must do the following when filling a Form 222 order:

- Enter information into company system.
- Annotate copies 2 and 3 with information on what was supplied.
- Log and track the form.
- Send copy 3 to DEA monthly.
- File and maintain copy 2 for two years.

The number of requisitions in 2007 was 88,699. For this ICR DEA reduced this number over the three years to reflect the shift to electronic orders. DEA does not anticipate that requisitions will fall as rapidly as paper orders because registrants may continue to maintain paper forms as a fallback.

The number of POA letters (130,890) is based on information provided by industry. DEA estimates that a fifth of the POA letters need to be issued each year.

Electronic Orders

For registrants that adopt the electronic ordering system, the following activities will occur:

- The purchaser will access the digital certificate (using a password), digitally sign, and archive each order. Digitally signing an order is done with a keystroke; archiving is assumed to take place automatically.
- The supplier will validate the order before filling it; validation is handled by the computer, with the only certificate holder action being a keystroke.
- Within two working days of filling orders, the suppliers' computers will either transmit copies of the orders to DEA or extract data on Schedule I and II orders from orders filled and transmit a computer-generated report on the orders to DEA.
- Installation of software or software patch to handle digitally signed orders.

The creation of the electronic order and the annotation of the record with information on the quantity shipped or received and data of shipping and receipt are not included because these activities are a necessary and usual part of business unlike the Form 222, which duplicates on paper the normal electronic records.

The number of respondents is the number of registrants issuing orders. The total number of activities is based on the number of orders (for ordering) and twice that number of annotating and filing. The number of times orders are sent to DEA is the number of suppliers (i.e., manufacturers, distributors, and importers) multiplied by 12 months for the paper system. Table 2 presents the number of annual activities.

Table 2: Number of Annual Activities

Activity	Number of Respondents	Activities per Respondent	Total Number of Activities	Total Number of Responses
Completing orders	96,280	1/order	3,724,122	96,280
Requisitioning Form 222s	82,490	Varies	82,490	82,490
Annotating and filing	96,280	1/order	7,448,245	96,280
Logging, tracking, and sending orders to DEA	557	12	6,684	557
POA letters	21,815	2 to 6/respondent/5 years	21,815	21,815
Software Installation	30 chains/year 8316 others	1	8,346	8,346
Total	96,280	1/order		

Burden Hours and Costs

To monetize time spent on various activities in either the paper or electronic system, wage rates were based on the latest industry information from the Bureau of Labor Statistics. Wage rates for suppliers (distributors, manufacturers, and importers) were based on drug wholesalers, because they issue more than 95 percent of the supplier orders; purchaser rates were based on pharmacists, because pharmacies issue most of the purchaser orders. The wage rates applied also vary with the type of activity performed. In the case of purchasers and suppliers, the wage rate depends on whether documents require completion by an authorized individual (i.e., a person with power of attorney) or are handled by clerks who process and file orders. Weighted wage rates were used for annotating and tracking. For software installation, a weighted wage rate was used to reflect the higher costs for chains that spend more time implementing software versus the majority of pharmacies where the software is installed by support personnel. All wages are in 2007 dollars, loaded with fringe benefits (37 percent for pharmacists, 46 percent for wholesalers) and inflated to the end of 2007 based on BLS data, and with overhead based on a survey of overhead rates for government contractors (49 percent of wages plus fringe). The wage rates are summarized in Table 3.

Table 3: Hourly Wage Rates

	Wage Rate	Source
Paper		
Execute order	$94.13	Pharmacist wage
Annotate, track order	$89.53	Weighted – pharmacist and drug wholesaler
File order	$25.51	Weighted – pharmacy tech and drug wholesaler clerk
Send to DEA	$84.93	Drug wholesaler purchasing manager
Execute POA letter	$58.96	Weighted – pharmacist and pharmacy tech
Electronic		
Execute order	$94.13	Pharmacist wage
Install software	$35.85	Weighted – pharmacy software developer and software support

Table 4 presents the unit hours and unit costs for the paper system and costs for electronic orders.

Table 4: Unit Costs

Activity	Hours	Unit Cost
Paper		
Complete and send order	0.25	$23.53
Requisition order	0.05	$4.71
Annotate order	0.05	$4.71
File orders	0.017	$0.40
Compile and send to DEA	9	$303
Execute POA letter	0.25	$23.53
Electronic		
Sign order	0.006	$0.56
Install software	8-40 hours	$284-$2,733

Annual burden hours per respondent vary widely depending mainly on the number of orders issued. Based ARCOS data, distributors issue about 500 orders a year, but presumably fill far than that. Pharmacies issue about 56 orders a year, hospitals about 37, and manufacturers about 22. Other registrant groups issue between 2 and 10 orders a year. Because the top 4 drug wholesalers control 69.9 percent of the market (based on the 2002 Economic Census), they may fill about 700,000 orders each. If the four issue the same proportion of orders, their annual burden would be 54,000 hours if all of the orders were paper and 17,500 hours if all orders were electronic. For pharmacies, the average annual burden would be 18 hours if the orders are paper and 2 hours if the orders are electronic.

To estimate the burden for the three years, DEA assumed that the total number of transactions (line items ordered) will increase by five percent a year (using 2007 as a base) and that the electronic transactions will double in the year 1 and increase 50 percent in each of years 2 and 3. The number of electronic transactions doubled from 2006 to 2007. DEA used transaction data rather than unique orders because of the disparity between the number of transactions on paper orders and the number on electronic orders. The number of electronic orders is derived by dividing the number of projected electronic transactions by 110, the average number of transactions per electronic order. The number of paper orders is derived by subtracting CSOS transactions from all transactions and dividing those by 4, the average number of transactions per paper order. Table 5 presents the data.

Table 5: Projected Paper and Electronic Orders Per Year

	222 Orders	CSOS Orders	All Transactions	CSOS Transactions
2008	3,668,230	55,892	20,821,043	6,148,122
2009	3,159,978	83,838	21,862,095	9,222,183
2010	2,280,481	125,757	22,955,200	13,833,275

Tables 6 through 8 present the total annual burden hours and labor costs by activity for the three years covered by this ICR. Table 9 presents the summary data.

Table 6: Year 1 Burden Hours and Labor Costs

ICR Year 1	Activities	Hours	Labor $
Paper			
Requisitions	82,490	1,375	$129,414
Execute orders	3,668,230	917,058	$86,323,062
Validate, annotate, log, track	7,336,461	366,823	$32,841,356
File	7,336,461	122,274	$3,119,494
Send to DEA	557	5,013	$425,743
POA	26,178	6,545	$385,869
Subtotal		**1,419,087**	**$123,224,937**
Electronic			
Execute orders	55,892	335	$31,567
Software installation	8,346	67,728	$2,428,015
Subtotal	**64,238**	**68,063**	**$2,459,582**
Total		**1,487,151**	**$125,684,520**

Table 7: Year 2 Burden Hours and Labor Costs

ICR Year 2	Activities	Hours	Labor $
Paper			
Requisitions	76,716	1,279	$120,355
Execute orders	3,159,978	789,995	$74,362,557
Validate, annotate, log, track	6,319,956	315,998	$28,291,017
File	6,319,956	105,333	$2,687,272
Send to DEA	557	5,013	$425,743
POA	26,178	6,545	$385,869
Subtotal		**1,224,161**	**$106,272,813**
Electronic			
Execute orders	83,838	503	$47,350
Software installation	12,519	101,112	$3,624,815
Subtotal		**101,615**	**$3,672,166**
Total		**1,325,776**	**$109,944,978**

Table 8: Year 3 Burden Hours and Labor Costs

ICR Year 3	Activities	Hours	Labor $
Paper			
Requisitions	71,346	1,189	$111,930
Execute orders	2,280,481	570,120	$53,665,697
Validate, annotate, log, track	4,560,963	228,048	$20,416,957
File	4,560,963	76,016	$1,939,340
Send to DEA	557	5,013	$425,743
POA	26,178	6,545	$385,869
Subtotal		**886,931**	**$76,945,538**
Electronic			
Execute orders	125,757	755	$71,025
Software installation	18,779	151,192	$5,420,158
Subtotal		**151,947**	**$5,491,184**
Total		**1,038,878**	**$82,436,722**

Table 9: Total Annual and Three-Year Hours and Labor Costs

Year	Total Burden Hours	Labor $
First	1,487,151	$125,684,520
Second	1,325,776	$109,944,978
Third	1,038,878	$82,436,722
Total	**3,851,804**	**$318,066,219**
Annual	**1,283,935**	**$106,022,073**

13. Estimate of Cost Burden:

Both suppliers and purchasers are required to retain a copy of each order for two years. The Form 222s must be retained on paper. A file cabinet that holds 1,150 files currently costs approximately $100; depreciated over 15 years, the annualized cost per file cabinet is $10.98. Approximately 13,672 file cabinets nationwide would be needed to store two years of orders. In addition, the file cabinets take space (about 2.75 square feet for a letter-sized file cabinet); the average rental cost per square foot is $20 for retail space (Marcus & Millichap 2007 National Retail Report).

O&M costs cover mailing orders to the suppliers and forms to DEA. Based on comments on the original CSOS rule, DEA assumes that 10 percent of orders are express shipped, 40 percent are mailed, and the rest are sent via the delivery truck (no charge). DEA assumes that requisitions are filed on line. Express shipped orders are assumed to be within the closest zone and to weigh no more than eight ounces ($13.25). There are no O&M costs attached to orders that are sent with the delivery truck. Orders shipped monthly to DEA are assumed to be express shipped, to weigh no more than 5 pounds, and to be shipped to the closest zone ($19.60).

For electronic orders, the cost of software would be a capital cost if it had to be purchased. Because almost all registrants already submit orders electronically for noncontrolled substances, the digital signing ability would be added to their software used to generate orders. There are about 20 pharmacy system providers; if each of them spent 2,000 hours to add digital signing capability and recovered the cost from the 63,000 pharmacy registrants the additional one-time charge would be at most about $12. Many registrants are likely to be given the signing software by distributors, who benefit from the use of electronic orders. DEA has no basis for determining whether and how the costs that third parties may incur will be recovered. The functionality may be added as a routine patch that is covered by standard maintenance charges. Because the costs are likely to be small if they are passed on, DEA has not included capital costs for the software. Registrants currently use computers to issue all orders except those that require a Form 222, so no additional equipment will be needed. The annual and three-year O&M costs have been estimated on the same basis as hours – that is, paper orders are phasing out as electronic orders phase in. Table 10 presents the costs for the three years covered by this ICR.

Table 10: Annual Capital and O&M Costs

	Capital	O&M	Total
Year 1			
Mailing orders		$5,432,649	$5,432,649
Mailing to DEA		$98,255	$98,255
Files and space	$149,848	$273,445	$423,292
Total	**$149,848**	**$5,804,348**	**$5,954,196**
Year 2			
Mailing orders		$4,730,487	$4,730,487
Mailing to DEA		$98,255	$98,255
Files and space	$130,152	$237,503	$367,654
Total	**$130,152**	**$5,066,245**	**$5,196,397**
Year 3			
Mailing orders		$3,413,881	$3,413,881
Mailing to DEA		$98,255	$98,255
Files and space	$103,700	$189,233	$292,933
Total	**$103,700**	**$3,701,369**	**$3,805,069**

Table 11 presents the three year and annual costs.

Table 11: Total Annual and Three Year O&M Costs

Year	Capital	O&M	Total
First	$149,848	$5,804,348	$5,954,196
Second	$130,152	$5,066,245	$5,196,397
Third	$103,700	$3,701,369	$3,805,069
Total	**$383,699**	**$14,571,962**	**$14,955,661**
Annual	**$127,900**	**$4,857,321**	**$4,985,220**

14. Estimated Annualized Cost to Federal Government:

Estimated annual cost to the Federal government for the Form 222 system:
Personnel salaries:
50 GS-7 1% of time = $391.27 per person = $19,563.72

Table 12: Federal Costs

	Labor Cost	Capital and O&M
Form 222		
Federal employees	$19,564	
Contractors		$72,000
Printing		$80,000

Mailing	$150,000
Data processing	$180,000
Equipment repairs	$15,000

TOTAL COST TO GOVERNMENT: $516,563 for Form 222. These costs will decline as registrants shift to electronic ordering. It should be noted that however DEA proceeds, there will be no actual cost to the Federal Government for these activities as all costs are recovered from registrants through registration fees, as required by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

Summary

Table 13 presents the burden hours and costs for the Form 222; there are no costs associated with requisitions (Form 222A) because they can be completed on line. The three-year cost assumes the phasing in of the electronic system discussed above. Table 14 presents the total burden hours, labor costs, and O&M costs for this ICR. Table 15 presents the average annual burden hours per registrant for issuing orders. Many registrants are likely to continue to issue orders both on paper and electronically over the period covered by this ICR depending on whether their suppliers accept electronic orders. It is, therefore, not possible to assign separate average burden hours to registrants based on the type of order issued.

Table 13: Total Hours and Costs for Forms

	Form 222	
Year	**Hours**	**Costs**
First	1,412,543	$122,839,068
Second	1,217,617	$105,886,943
Third	880,387	$76,559,668
Total	**3,510,546**	**$305,285,680**
Annual	**1,170,182**	**$101,761,893**

Table 14: Summary of Burden Hours and Costs

Year	Total Burden Hours	Labor	Other Costs	Total
First	1,487,151	$125,684,520	$5,954,196	$131,638,716
Second	1,325,776	$109,944,978	$5,196,397	$115,141,375
Third	1,038,878	$82,436,722	$3,805,069	$86,241,790
Total	**3,851,804**	**$318,066,219**	**$14,955,661**	**$333,021,881**
Annual	**1,283,935**	**$106,022,073**	**$4,985,220**	**$111,007,294**

Table 15: Average Annual Hour per Respondent

Year	# Registrants	Total Hours
First	96,280	1,487,151
Second	96,280	1,325,776
Third	96,280	1,038,878
Annual Hours		**1,283,935**
Average Annual Hours/Registrant		**13.34**
Average # of Orders/ Registrant		**32.45**

Table 16: Average Annual Cost per Respondent

	# Registrants	
	96,280	
	96,280	
	96,280	
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15. Reasons for Change in Burden:

DEA is allowing, but not mandating, the use of electronic orders for Schedule I and II controlled substances. The implementation of electronic ordering is occurring more slowly than DEA projected originally, but the number of transactions per electronic order is significantly higher than the number of transactions per paper order. As a result, the burden hours have declined.

16. Plans for Publication:

There are no plans to publish the information.

17. Expiration Date Approval:

It would be an administrative burden to replace existing forms when nothing of substance changed except date of expiration. Therefore, approval is requested not to display date of Expiration on Forms 222 and 222a.

18. Exceptions to the Certification Statement:

There are no exceptions to the certification statement.

Part B. Statistical Methods

The Drug Enforcement Administration will not be employing statistical methods in this information collection.