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
DEA Form 222, Controlled Substances Ordering System
1117-0010

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 Controlled Substances Ordering System (CSOS).) 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.

For the period used for this supporting statement, the approximately 4.9 million paper orders represented about 26.6 million transactions (or about 5 per order); the approximately 152,000 electronic orders represented about 13 million transactions or slightly more than 86 per order. Whereas paper orders are restricted to no more than ten transactions per order (ten line items per form), electronic orders are not subject to the same requirement and may contain an unlimited number of transactions (line items) per order. Thus, for the period used for this supporting statement, electronic orders represented32.8 percent of all orders.

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:

There are no circumstances that require the collection of data that would be inconsistent with the guidelines set forth in 5 CFR 1320.6. DEA meets regularly with the affected industry to discuss policies, programs and regulations.

9. Payment or Gift to Claimants:

There are no such payments or gifts to respondents.

10. Assurance of Confidentiality:

DEA Forms 222 are used for business transactions between purchasers of controlled substances and suppliers of controlled substances. Copies of those forms are provided to DEA. The information contained on those forms is considered business records of the purchasers and suppliers. 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 calendar year 2010. 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. DEA assumes six people with POA per manufacturer and per distributor, two people with POA per hospital/clinic and per teaching institution, and one person with POA per exporter and per analyst.

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	243	1,458
Distributors	394	2,364
Importers	6	N/A
Hospitals/Clinics	10,787	21,574
Pharmacies*	63,412	105,688
Teaching Institutions	67	134
Exporters	62	62
Narcotic Treatment Programs, Researchers, Chemical Analysts	2,627	2,627
Practitioners	32,034	N/A
TOTAL	**109,632**	**133,907**

* Pharmacies include 52,832 individual pharmacies with two POAs each, and 10,580 chain pharmacies for which orders are processed centrally involving six POAs for each chain (24 POAs for the four chains).

For the purposes of this supporting statement, DEA defines the number of respondents to the forms as the number of registrants.

Activities

This ICR includes details on activities for both paper and electronic orders because DEA registrants are adopting electronic orders over time. As previously noted, based on unique order numbers processed through ARCOS, about 4.9 million orders were processed on Form 222s and 152,000 were processed electronically. The paper orders represented about 26.6 million

transactions (or about 5 per order); the electronic orders represented about 13 million transactions or slightly more than 86 per order. Note that the DEA Form 222 permits ten line items per form; electronic orders are not subject to the same requirement and may contain an unlimited number of transactions (line items).

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.

In 2010, the number of requisitions submitted to DEA was 90,966. .

In 2010, the number of respondents that logged, tracked, and sent orders to DEA was 581 – the total number of manufacturers, distributors, and reverse distributors.

The number of POA letters (133,910) is based on information provided by industry. DEA estimates that a fifth of the POA letters need to be issued each year, or about 26,781 annually.

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.

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 area 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 Annual Number of Activities	Total Annual Number of Responses
Completing orders	109,632	1/order	5,090,371	109,632
Requisitioning Form 222s	90,966	Varies	90,966	90,966
Annotating and filing**	109,632	1/order	10,180,742	109,632
Logging, tracking, and sending orders to DEA	581*	12	6,972	581
POA letters	26,781	2 to 6/respondent/5 years	21,815	26,781
Total***	109,632	1/order		109,632

* Some registrants may purchase Schedule I and II controlled substances but may not sell Schedule I and II controlled substances. The most likely reason is that the Schedule I or II substances is manufactured into a substance not in one of those schedules.

** Both suppliers and purchasers must annotate their individual copy of the DEA Form 222. Thus, the annotating requirement occurs once per order for purchasers and once per order for suppliers, doubling the overall count.

*** As has been discussed, 109,632 registrants participate as either purchasers or suppliers in this system. These registrants complete at least some, but not necessarily all, activities listed above. Individual registrants may place (purchase) or fill (supply) orders throughout the year, using the forms on an as-needed basis. Activities associated with orders occur once per order. Other activities, including issuance of POA letters, occur on an as-needed basis less frequently than orders.

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. Activities are

divided about equally among pharmacists and purchasing managers (for wholesalers) and pharmacy technicians and order clerks. For simplicity, a single wage rate was developed that included the median wage rate for each labor category, loaded with fringe at 40 percent and overhead at 56 percent for an average loaded compensation of $70.21. Rates were obtained from BLS Occupational Employment Statistics and BLS Employer Costs for Employee Compensation.

Table 3presents the unit hours and unit costs for the paper system and costs for electronic orders.

Table 3: Unit Costs

Activity	**Hours**	Unit Cost
Paper		
Complete and send order	0.25	$17.55
Requisition order	0.05	$3.51
Annotate order	0.05	$3.51
File orders	0.017	$1.19
Compile and send to DEA	9	$631.89
Execute POA letter	0.25	$17.55
Electronic	0.006	$0.42

To estimate the burden for the three years, DEA assumed that the total number of transactions and orders will remain constant. This is conservative, because as registrants shift to electronic orders, the number of orders declines. Table 4 presents the data.

Table 4: Projected Paper and Electronic Orders*

222 Orders	**CSOS Orders**	**All Transactions**	**CSOS Transactions**
4,900,000	155,000	40,000,000	14,000,000

* These projections are based on rounded totals from 2010.

Table 5 presents the total annual burden hours and labor costs by activity for years covered by this ICR. Table 6 presents the 3-year costs.

Table 5: Burden Hours and Labor Costs

ICR	**Activities**	**Hours**	**Labor $**
Paper			
Requisitions	90,966	4,548	$319,337
Execute orders	4,900,000	1,225,000	$86,007,422

Validate, annotate, log, track	9,800,000	490,000	$34,402,969
File	9,800,000	166,600	$11,697,009
Send to DEA	581	5,229	$367,129
POA	26,781	6,695	$470,081
Subtotal		**1,898,073**	**$133,263,946**
Electronic Orders	155,000	930	$65,295
Total		**1,899,003**	**$133,329,242**

Table 6: Total Annual and Three-Year Hours and Labor Costs

Year	**Total Burden Hours**	**Labor $**
First	1,899,003	$133,329,242
Second	1,899,003	$133,329,242
Third	1,899,003	$133,329,242
Total	**5,697,008**	**$399,987,726**
Annual	**1,899,003**	**$133,329,242**
Average annual hours/Registrant	**17.33**	

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 $165; depreciated over 15 years, the annualized cost per file cabinet is $11. Approximately 17,043 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).

Operation &Maintenance 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. FedEx standard overnight shipped orders are assumed to be within the closest zone and to weigh no more than eight ounces ($15.50). Mailed orders are assumed to cost $0.44 for postage per order and $0.06 per envelope. 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 ($22.60)(FedEx standard overnight).

Table 7 presents the annual costs.

Table 7: Annual and 3-Year Capital and O&M Costs

	Capital	O&M	Total
Mailing orders		$8,575,000	$8,575,000
Mailing to DEA		$118,175	$118,175
Files and space	$187,478	$937,391	$1,124,870
Total	**$187,478**	**$9,630,567**	**$9,818,045**
3-Year	**$562,435**	**$28,891,700**	**$29,454,135**

14. Estimated Annualized Cost to Federal Government:

Estimated annual cost to the Federal government for the Form 222 system:

Government Employees:	$959.89
Contract Employees:	$86,030.40
Cost of Forms:	$236,835.68
Mailing (Postage):	$1,165,833.22
Custom Envelopes	$35,515.29
Printer Maintenance:	$31,480
Printers/10 years:	$16,003

Total: $1,572,657.48

It should be noted that the Federal Government recovers these costs 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 8 presents the burden hours and costs for the Form 222 and the ordering aspects of the Controlled Substances Ordering System (electronic orders). Table 9 presents the total burden hours, labor costs, and O&M costs for this ICR. Table 10 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 8: Total Hours and Costs for Forms

Form 222	
Hours	**Costs**
1,898,073	$133,263,946

Electronic orders	
930	$65,295

Table 9: Summary of Burden Hours and Costs

Year	Total Burden Hours	Labor	Other Costs	Total
Annual	1,899,003	$133,329,242	$9,818,045	$143,147,287
Three Year	5,697,009	$399,987,726	$29,454,135	$429,441,861

Table 10: Average Annual Hour per Respondent

	# Registrants	Total Hours
	109,632	**1,899,003**
Average Annual Hours/Registrant		**17.33**
Average # of Orders/ Registrant		**46**

Table 11: Average Annual Cost per Respondent

Year	# Registrants	Other Costs
Annual Costs	**109,632**	**$9,818,045**
Average Annual Cost/Registrant		**$89.55**

15. Reasons for Change in Burden:

DEA is adjusting burden hours to reflect actual orders issued in calendar year 2010. These changes reflect population adjustments related to normal business activity. There were no statutory or regulatory changes related to this information collection.

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 Forms222 and 222a. DEA will update electronic forms with the date of expiration for this information collection upon approval.

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.