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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1305

[Docket No. DEA–453]

RIN 1117-AB44

New Single-Sheet Format for U.S. Official Order Form for Schedule I and II Controlled Substances (DEA Form 222)

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. DEA published a notice of proposed rulemaking about this new format in November 2007 but did not finalize it. Due to the passage of time and procedural considerations, DEA is reissuing another notice of proposed rulemaking. This proposal supersedes the November 2007 proposal. This proposed rule calls for allowing the continued use of the existing triplicate DEA Form 222 until a sunset date of two years after the final rule becomes effective, which would be included in the final rule. DEA also proposes minor procedural changes, including among other things, to clarify the procedure involving who can issue the power of attorney that is required for others to sign DEA Form 222.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE FEDERAL REGISTER]. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–453" on all correspondence, including any attachments.

Electronic comments: The Drug Enforcement Administration encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the Web page or to attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions to submit comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on Regulations.gov. If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

Paper comments: Paper comments that duplicate an electronic submission are not necessary and are discouraged. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT: Kathy L. Federico, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration for public inspection online at *http://www.regulations.gov*. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act (FOIA) applies to all comments received. 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 made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place the personal identifying information you do not want to be made publicly available 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 made publicly available, 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.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone

number) or confidential business information included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document is available at *http://www.regulations.gov* for easy reference.

Legal Authority and Background

The Controlled Substances Act (CSA) grants the Attorney General authority to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances (21 U.S.C. 821); maintenance and submission of records and reports (21 U.S.C. 827); and for the efficient execution of his statutory functions (21 U.S.C. 871(b)). The Attorney General is further authorized by the CSA to promulgate rules and regulations relating to the registration and control of importers and exporters of controlled substances. 21 U.S.C. 958(f). The Attorney General has delegated these authorities to the Administrator of the DEA. 28 CFR 0.100(b).

The DEA previously published a notice of proposed rulemaking (NPRM) on this matter in the Federal Register on November 27, 2007 (72 FR 66118). The rulemaking proposed revising the DEA regulations to implement a new format for order forms (DEA Form 222) – issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances – by replacing the three-part carbon-copy form with a single sheet form. During the comment period, DEA received comments from six entities: an organization representing pharmacists, an organization representing pharmaceutical manufacturers and distributors, a pharmaceutical distributor, two reverse distributors, and one individual. Two commenters opposed the proposed rule as written, one supported it

with significant concerns, two commenters requested simply the number of line items on the DEA Form 222 be expanded, and one commenter supported the rule and had specific questions regarding distribution of copies for reverse distributors.

The DEA is reissuing another NPRM, superseding the November 2007 NPRM. In this NRPM, the DEA also proposes minor changes to clarify who can issue the power of attorney (POA) that is required for others to sign DEA Form 222.

Order Forms

The CSA requires that schedule I and II controlled substances be only distributed pursuant to a written order made by the purchaser on a form issued by the Attorney General. 21 U.S.C. 828(a). This responsibility has been delegated to the Administrator of DEA (28 CFR 0.100(b)) and redelegated to the Deputy Assistant Administrator of the DEA Diversion Control Division (28 CFR 0.104; section 7(d) of 28 CFR part 0, appendix to subpart R).[1] The DEA uses these order forms to allow tracking of distributions of schedule I and II controlled substances.

Order forms are required for distribution of schedule I and II controlled substances. 21 U.S.C. 828(a); 21 CFR 1305.03. The order forms are issued by DEA to authorized DEA registrants to allow distribution of schedule I and II controlled substances. The order forms are designated as DEA Form 222. The regulations stipulate the forms will be serially numbered and issued with the name, address, and registration number of the registrant, the authorized activity, and the schedules of the registrant (21 CFR

[1] The introductory text of section 7 of 28 CFR part 0, appendix to subpart R allows for the redelegation of responsibility to the Deputy Assistant Administrator of the DEA Office of Diversion Control. However, this office has been reorganized to the DEA Diversion Control Division.

1305.11(d)). Currently, order forms are three-part carbon forms, printed on interleaved carbon sheets, hereafter also referred to as current or triplicate forms.

Whenever a DEA registrant wishes to acquire a schedule I and/or II controlled substance, that registrant must complete the order form, pursuant to the form instructions, to include the name and address of the supplying DEA registrant, the date requested, the number of packages of controlled substance(s) ordered, the size of the package of the controlled substance(s) ordered, and the name of the controlled substance(s) ordered. Under the current procedures outlined in 21 CFR 1305.13(a), (b), (d), and (e), the purchaser retains one copy (Copy 3) of the triplicate form and sends two copies (Copy 1 and Copy 2) to the supplier so that the order for a controlled substance can be filled. The supplier completes the form by entering the actual number of packages of the controlled substance(s) shipped and the actual date shipped. The supplier retains one copy (Copy 1) of the order form sent to him/her by the purchaser, and sends the other copy (Copy 2) of the order form to the DEA Special Agent in Charge in the area where the supplier is located. Upon receiving the controlled substance(s), the purchaser writes the number of packages of the controlled substance(s) ordered which are actually received and the date received on its copy (Copy 3). Under current 21 CFR 1305.17(a) through (c), both the purchaser and the supplier must preserve their respective copy of the order form for two years and make it available to officials of the DEA for inspection, if requested.

Justification for New Order Form

The proposed new format for DEA Form 222 would employ a single-sheet form, hereafter also referred to as the new form(s). In executing a transaction involving a schedule I and/or II controlled substance, a DEA registrant (purchaser) would process the

new single-sheet form in a similar manner to the processing of the current form. The proposed changes in processing include the purchaser retaining a readily retrievable copy, in which copies can be scanned and stored electronically rather than retaining the pre-printed carbon copy. In addition, any registrant supplier who is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) would be required to make and submit a copy of the original DEA Form 222 to DEA by mail, fax, or email instead of the supplier sending a copy of the original order form. This proposed procedure would replace requiring all suppliers, regardless of ARCOS reporting requirements, to submit Copy 2 to the DEA Special Agent in charge in the area where the supplier is located. The purchaser and supplier would preserve the original order form and a copy of the original order form, respectively, for two years and make it available to officials of the DEA for inspection, if requested. DEA would continue to preprint and issue the new forms.

The single-sheet form would have an issued order form number with enhanced security features over the current form. DEA would preprint the new single-sheet form on security paper to ensure the identity of the original while making it difficult to copy for counterfeit purposes.

The single-sheet form will be more convenient for DEA registrants to utilize. The current format was created more than forty years ago and processing a transaction with carbon copies is outdated. Today, new office technology exists, such as laser printers, scanners and photocopiers, which will allow DEA registrants greater ease in utilizing the single-sheet form.

The single-sheet form will benefit DEA as well. There is only one vendor that produces the current three-part carbon forms which is costly. The Dot Matrix printer used to print the forms is outdated, and DEA can only get replacement parts from one vendor. Maintaining the equipment is costly, difficult, and time-consuming.

Transition from Current to New Order Form

If this regulation is finalized, the new single-sheet form will be used, and DEA would not issue any more triplicate forms. DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition period. When a registrant's supply of triplicate forms is depleted, the DEA would issue the new single-sheet forms. The final rule would include a "sunset date" – a date after which use of the triplicate forms would not be allowed – of two years after the final rule becomes effective. Thus, business firms will have time to shift their processes to accommodate the new single form. For clarity, this rule would revise the existing regulations in part 1305, subpart B to follow the procedures for the issuance and use of the new single-sheet form for the future. The transition procedures allowing the continued use of existing supplies of the triplicate DEA Form 222 would be relocated to a new § 1305.20.

Revision of DEA Regulations to Accommodate New Order Form

DEA proposes to amend its regulations pertaining to orders for schedule I and II controlled substances, set forth in 21 CFR part 1305, to provide for the use of the single-sheet DEA Form 222. As discussed above, to ease the transition, DEA will allow the continued use of existing stocks of the triplicate forms for a two year transition period.

DEA proposes to amend its regulations to reflect that only one original DEA Form 222 will be provided to authorized registrants by DEA. If finalized, registrants that wish

to obtain schedule I and II controlled substances (purchasers) would be required to complete and retain a copy of the form and send the original to their supplier for filling. The supplier would be required to record certain information related to the filling on the original and retain such original. In addition, any supplier who is not required to report acquisition/distribution transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) (such as a practitioner) would be required to make and submit a copy of the original DEA Form 222 to DEA by mail (Drug Enforcement Administration, Attn: Registration Section/ DRR, P.O. Box 2639, Springfield, VA 22152-2639), fax to (202) 307-5602 or email to DEA.Orderforms@usdoj.gov. The purchaser would be required to record on their copy of the single-sheet form certain information related to the items furnished by the supplier. It is important to note that the process for handling the DEA Forms 222 remains unchanged. The only changes made by these proposed amendments, if finalized, are to require purchasers and suppliers to retain the original of the single-sheet form or to make and retain readily retrievable copies of the form, as applicable, rather than retaining the pre-printed carbon copies. If finalized, the rule also would provide other general procedures related to the single-sheet form (e.g., endorsing forms, cancelling forms, lost or stolen forms, unaccepted or defective forms).

Currently, triplicate forms are issued in mailing envelopes containing seven forms (informally referred to as "books"). The new single-sheet form will not be produced in "books," giving DEA and registrants greater flexibility to request a specific number of order forms. Therefore, in § 1305.11(a), DEA is proposing to modify the language regarding the new single-sheet DEA Form 222 to indicate that a predetermined number

of order forms, based on the business activity of the registrant, will be issued, rather than the current "books" of seven order forms. DEA also proposes to revise § 1305.11(c) to remove language pertaining to "books of DEA Forms 222."

Other Minor Regulatory Changes

The DEA is proposing several minor regulatory changes as part of this rulemaking, as discussed below.

Pursuant to § 1305.05(a), a registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for schedule I and II controlled substances on the registrant's behalf by executing a power of attorney (POA) for each such individual, if the POA is retained in the files, with executed DEA Forms 222 where applicable, for the same period as any order bearing the signature of the POA. The POA must be available for inspection together with other order records.

Under § 1305.05(d), a POA must be executed by the person who signed the most recent application for DEA registration or reregistration; the person to whom the POA is being granted; and two witnesses. DEA proposes to modify this language to increase the accountability to permit other individuals to authorize the POA on behalf of the registrant who is unavailable and is similar to the language found in 21 CFR 1301.13(j) regarding who can sign an application for a DEA registration. For example, if the legal entity that is applying for a DEA registration is a partnership, then either partner may sign the application. If the legal entity that is applying for a DEA registration is a corporation, then any corporate officer may sign the application. DEA is proposing to allow the registrant, if an individual, to execute a POA even though that individual did not sign the last application.

In §1305.11(b), DEA is proposing to revise the procedure for requisitioning DEA Forms 222 by any person with an active registration that is authorized to order schedule I and II controlled substances to include obtaining them through a secured network connection. As previously discussed, DEA would only be issuing single-sheet forms if the proposed rule were finalized. Due to the advancement of technology, the Diversion Control Division can look at other methods and procedures when single-sheet forms are requested only through a secured network connection between devices. In §1305.11(d), DEA is proposing to add procedures for reporting any errors on a DEA Form 222 to the local Division Office.

In § 1305.12(a), DEA is proposing to add a "computer printer" to the list of acceptable methods for filling out a DEA Form 222, in addition to the existing use of a typewriter, pen, or indelible pencil.

Currently, § 1305.13(d) preserves triplicate copies of DEA Form 222 for the supplier. DEA proposes to modify the language to a single-sheet form. A single-sheet Form 222 needs to be available for inspection for a period of two years in accordance with proposed § 1305.17(c).

In § 1305.14(b), DEA is proposing to remove the exception where the name of the supplier is requested on the reporting form, the second supplier must record the name, address, and registration number of the first supplier. DEA has noticed that distribution centers, when reporting to ARCOS, would report themselves as the supplier and not try to record the name, address, and registration number of the first supplier. DEA believes that removing this exception would enable more accurate reporting and recordkeeping.

Regulatory Analysis

DEA conducted a regulatory analysis of the proposed rule to determine how its provisions will impact registrants and the DEA. The results of this analysis are outlined below.

Executive Orders 12866 (Regulatory Planning and Review), 13563, (Improving Regulation and Regulatory Review), and 13771(Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders 12866, 13563 and 13771. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in Executive Order 12866. Executive Order 12866 classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of

legal mandates, the President's priorities, or the principles set forth in the Executive Order.

1. The DEA expects that this proposed rule will not have an annual effect on the economy of $100 million or more in at least one year and therefore is not an economically significant regulatory action. DEA's analysis finds that this proposed rule will result in an annual cost-savings of $25.9 million; approximately $22.1 million to purchasers (persons executing DEA Form 222s) primarily due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use; approximately $0.2 million to non-dispensing suppliers (manufacturers and distributors) due to the elimination of the requirement that registrants mail copies of their completed order forms to their DEA field office; $2.9 million to dispensing suppliers due to having the option to fax or scan-and-email completed order forms; and $0.8 million to DEA from reduction in cost of forms production, postage, and equipment maintenance.

2. This regulatory action is not likely to result in a rule that may create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

3. This regulatory action is not likely to result in a rule that may materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

4. This regulatory action is not likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This proposed rule is estimated to have a total cost savings of $25.9 million. Although this proposed rule is not a significant regulatory action under EO 12866, this proposed rule is expected to be an EO 13771 deregulatory action.

An economic analysis of the proposed rule can be found in the rulemaking docket at http://www.regulations.gov.

Executive Order 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments

This proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator hereby certifies that this proposed rule has been drafted, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it, certifies that this rule will not, if promulgated, have a significant economic impact upon a substantial number of small entities.

In accordance with the RFA, the DEA evaluated the impact of this rule on small entities. The DEA is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. DEA also proposes minor procedural changes, including among other things, who can issue the power of attorney that is required for others to sign DEA Form 222. This proposed rule affects all parties (purchaser and suppliers) to transactions where a DEA Form 222 is used.

Based on its records, the DEA estimates that 71,481 entities are affected by this rule, which consist of 336 manufacturers, 378 distributors, 31,887 pharmacies, 7,980 hospitals and clinics and 30,900 practitioners. The DEA estimates that 65,984 (92.3%) of the total 71,481 affected entities are small entities (312 manufacturers, 364 distributors, 31,217 pharmacies, 3,716 hospitals and clinics and 30,375 practitioners). The estimated economic impact varies for purchasers and suppliers, and among the suppliers, dispensing suppliers and non-dispensing suppliers.

"Purchasers" are registrants (primarily pharmacies, practitioners, hospitals and clinics) who execute DEA Form 222 to order Schedules I and II controlled substances. The use of the new single sheet form will require purchasers to make a copy (photocopy or scan) prior to submission to a supplier at an estimated cost of $0.22 per form, or a total of $734,646 per year. However, some cost savings are expected due to efficiencies gained from the new form. Key advantages include: 1) reduction in number of forms executed due to increased number of lines per form, 2) reduction in form failure due to upgraded high-quality secure paper (fewer incidences of tears, carbon not copying through, improper tear of perforated edges, etc.), and 3) increased efficiency in completing the

form due to ability to use a computer printer to fill the form (in addition to the existing allowable methods of typewriter, pen, or indelible pencil). Purchasers, as a group, are anticipated to save $22,794,750, for a net savings of $22,060,104, or $312 per entity.

"Dispensing suppliers" are individual or institutional practitioners (e.g. physicians, pharmacies, hospitals, clinics, etc.) that are registered to dispense a controlled substance and may also distribute (without being registered to distribute) a quantity of such substance to another practitioner using a DEA Form 222. The proposed rule would allow the dispensing supplier to submit their copy of the order form to DEA via fax or email, in addition to the currently required submission by mail. Assuming dispensers will opt for the less costly fax or scan-and-email method, based on an estimated 17,480 dispensing suppliers, the DEA estimates the dispensing suppliers, as a group, would save $2,861,977 per year or $164 per supplier.

"Non-dispensing suppliers" are persons registered with the DEA as manufacturers or distributors of controlled substances listed in Schedules I or II. The proposed rule and new form would remove the requirement to ship their copies of the received order forms to their DEA field office at the end of each month. The DEA estimates, by removing this requirement, the non-dispensing suppliers, as a group would save $239,657 per year, or $336 per entity.

In summary, the proposed rule is estimated to save Purchasers, Dispensing Suppliers, and Non-Dispensing Suppliers, $312, $164, and $336 per entity per year, respectively. The DEA uses 3% of annual revenue as threshold for "significant economic impact." The annual revenue at which $312, $164, and $336 is 3% equates to $10,400, $5,467, and $11,200, respectively. The DEA estimates the annual revenues of purchasers, dispensing

suppliers, and non-dispensing suppliers are greater than $10,400, $5,467, and $11,200, respectively, resulting in an economic impact of less than 3% of annual revenue.

Therefore, the DEA's evaluation of economic impact by size category indicates that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted 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, 2 U.S.C. 1532.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), the DEA has identified the following collections of information related to this proposed rule. A person is not required to respond to a collection of information unless it displays a valid Office of Management and Budget (OMB) control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain*.

A. *Collections of Information Associated with the Notice of Proposed Rulemaking*

Title: U.S. Official Order Forms for Schedules I & II Controlled Substances (Accountable Forms), Order Form Requisition

OMB Control Number: 1117-0010

Form Number: DEA-222

The DEA Form 222 provides the DEA with oversight and control over the distribution of schedules I and II controlled substances. The form is the only document that can authorize the distribution of schedules I and II controlled substances within the closed system of distribution. The DEA is proposing to amend its regulations to implement a new single-sheet format for order forms (DEA Form 222) which are issued by DEA to DEA registrants to allow them to order schedule I and/or II controlled substances. Currently, the DEA Form 222 is a triplicate form with interleaved carbon paper.

The new single-sheet format is expected to lower labor burden due to efficiencies gained from having more lines per form, anticipated reduction of instances of form failure, allowing the use of a printer, and general ease of use. Additionally, the proposed rule removes the requirement for Automation of Reports and Consolidated Orders System (ARCOS)-reporting suppliers to mail/ship completed order forms to the DEA field offices. Finally, the proposed rule would also allow non-ARCOS reporting suppliers (generally dispensers who distribute) to submit completed order forms to the respective DEA field offices via fax or email, in addition to mail.

DEA registrants will be allowed to exhaust their supply of the current forms as part of the transition period. When a registrant's supply of triplicate forms is depleted, the DEA would issue the new single-sheet forms. The final rule would include a "sunset date" – a date after which use of the triplicate forms would not be allowed – of two years after the final rule becomes effective.

This proposed rule does not impact those who use the electronic equivalent order form. The DEA estimates the following number of respondents and burden associated

with this collection of information (which includes DEA Form 222 and the electronic equivalent):

- Number of respondents: **125,435**
- Frequency of response: **59**
- Number of responses: **7,400,000 (3,300,000 paper DEA Form 222, 4,100,000 electronic equivalent)**
- Burden per response: **$0.1392**
- Total annual hour burden: **1,030,000**

Due to the elimination for suppliers to mail completed DEA Form 222 to the local DEA field office, the Cost Burden is also eliminated. Due to the provisions of this proposed rule requiring purchasers to make copies of the new single-sheet format for order forms (DEA Form 222), the cost is reduced to $130,350.

B. *Request for Comments Regarding the Proposed Collections of Information*

Written comments and suggestions from the public and affected entities concerning the proposed collections of information are encouraged. Under the PRA, the DEA is required to provide a notice regarding the proposed collections of information in the *Federal Register* with the Notice of Proposed Rulemaking and solicit public comment. Pursuant to section 3506(c)(2) of the PRA (44 U.S.C. 3506(c)(2)), the DEA solicits comment on the following issues:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the DEA, including whether the information will have practical utility.

- The accuracy of the DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Recommendations to enhance the quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117-0010/Docket No. DEA-453. All comments must be submitted to OMB on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

Congressional Review Act

This proposed rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This proposed 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 1305

Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set forth above, the DEA proposes to amend 21 CFR part 1305 as follows:

PART 1305—ORDERS FOR SCHEDULE I AND II CONTROLLED SUBSTANCES

1. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

2. Amend § 1305.05 by revising paragraph (d) to read as follows:

§ 1305.05 Power of attorney.

* * * * *

(d) A power of attorney must be executed by the registrant, if an individual; by a partner of the registrant, if a partnership; or by an officer of the registrant, if a corporation, corporate division, association, trust or other entity; the person to whom the power of attorney is being granted; and two witnesses.

* * * * *

3. Revise § 1305.11 to read as follows:

§ 1305.11 Procedure for obtaining DEA Forms 222.

(a) DEA Forms 222 are issued in mailing envelopes containing a predetermined number of forms based on the business activity of the registrant, each form consisting of one single-sheet. A limit, which is based on the business activity of the registrant, will be imposed on the number of DEA Forms 222 which will be furnished on any requisition unless additional forms are specifically requested and a reasonable need for such additional forms is shown.

(b) Any person with an active registration that is authorized to order schedule I and II controlled substances would be entitled to obtain a DEA Form 222, which will be supplied at any time after the DEA registration is granted. Any person holding a registration authorizing him or her to obtain a DEA Form 222 may requisition the forms through a DEA secured network connection or by contacting any Division Office or the Registration Section of the Administration through the customer service center.

(c) Each requisition must show the name, address, and registration number of the registrant and the number of DEA Forms 222 desired. Each requisition must be signed and dated by the same person who signed the most recent application for registration or for reregistration, or by any person authorized to obtain and execute DEA Forms 222 by a power of attorney under § 1305.05.

(d) DEA Forms 222 will have an order form number and be issued with the name, address and registration number of the registrant, the authorized activity, and schedules of the registrant. This information cannot be altered or changed by the registrant; the registrant must report any errors to the local Division Office or the Registration Section of the Administration to modify the registration.

4. Amend § 1305.12 by revising paragraph (a) to read as follows:

§ 1305.12 Procedure for executing DEA Forms 222.

(a) A purchaser must prepare and execute a DEA Form 222 by use of a typewriter, computer printer, pen, or indelible pencil.

* * * * *

5. Amend § 1305.13 by revising paragraphs (a), (b), (d), and (e) to read as follows:

§ 1305.13 Procedure for filling DEA Forms 222.

(a) A purchaser must submit the original DEA Form 222 to the supplier and retain a copy in the purchaser's files.

(b) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on the original and a copy their DEA registration number and the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (f) of this section.

* * * * *

(d) The supplier must retain the original DEA Form 222 for his or her files in accordance with §1305.17(c). Any supplier who is not required to report acquisition/disposition transactions to the Automation of Reports and Consolidated Orders System (ARCOS) under § 1304.33(c) of this chapter (such as a practitioner) must make and submit a copy of the original DEA Form 222 to DEA by mail (Drug Enforcement Administration, Attn: Registration Section/DRR), fax (202) 307-5602), or email to (DEA.Orderforms@usdoj.gov). The copy must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, the copy must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(e) The purchaser must record on its copy of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

* * * * *

6. Amend § 1305.14 by revising the first two sentences of paragraph (a) and paragraph (b) to read as follows:

§ 1305.14 Procedure for endorsing DEA Forms 222.

(a) A DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in § 1305.13, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided in Part 3 on the original DEA Form 222) the DEA number of the second supplier, and must be signed and dated by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. * * *

(b) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

7. Amend § 1305.15 by revising paragraphs (b) and (d) to read as follows:

§ 1305.15 Unaccepted and defective DEA Forms 222.

* * * * *

(b) If a DEA Form 222 cannot be filled for any reason under this section, the supplier must return the original DEA Form 222 to the purchaser with a statement as to the reason (e.g. illegible or altered).

* * * * *

(d) When a purchaser receives an unaccepted order, the original DEA Form 222 and the statement must be retained in the files of the purchaser in accordance with § 1305.17.

A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

8. Amend § 1305.16 by revising paragraphs (a) and (d) to read as follows:

§ 1305.16 Lost and stolen DEA Forms 222.

(a) If a purchaser ascertains that an unfilled DEA Form 222 has been lost, he or she must execute another and attach a statement containing the order form number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. A copy of the second form and a copy of the statement must be retained with a copy of the DEA Form 222 first executed. A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return the original DEA Form 222 to the purchaser, who must attach it to the statement.

* * * * *

(d) If any DEA Forms 222 are lost or stolen, and the purchaser is unable to state the order form numbers of the DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or approximate date of issuance.

* * * * *

9. Amend § 1305.17 by revising paragraphs (a), (b), and (c) to read as follows:

§ 1305.17 Preservation of DEA Forms 222.

(a) The purchaser must retain a copy of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(b) The supplier must retain the original of each DEA Form 222 that it has filled.

(c) DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain a copy of the executed DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under § 1305.12(e)), at the registered location printed on the DEA Form 222.

* * * * *

10. Amend § 1305.19 by revising paragraph (a) to read as follows:

§ 1305.19 Cancellation and voiding of DEA Forms 222.

(a) A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

* * * * *

11. Add § 1305.20 to read as follows:

§ 1305.20 Transition provisions allowing continued use of existing stocks of triplicate DEA Forms 222.

This section provides the procedures allowing registrants to continue to use existing stocks of the triplicate DEA Form 222, which may continue to be used until [Sunset Date of two years after effective date of final rule]. Registrants are required to use the new single-sheet DEA Form 222 once the supply of the triplicate forms is exhausted. The provisions of this part are applicable to the use of triplicate forms, except for the specific rules as provided in this section.

(a) *Procedure for obtaining DEA Forms 222.* As set forth in § 1305.11, DEA will no longer issue triplicate forms. Triplicate DEA Forms 222 will not be accepted after [Sunset Date of two years after effective date of final rule].

(b) *Procedure for executing the triplicate DEA Forms 222.* As set forth in § 1305.12:

(1) A purchaser must prepare and execute a triplicate DEA Form 222 simultaneously by means of interleaved carbon sheets that are part of the DEA Form 222. DEA Form 222 must be prepared by use of a typewriter, pen, or indelible pencil.

(2) Only one item may be entered on each numbered line. An item must consist of one or more commercial or bulk containers of the same finished or bulk form and quantity of the same substance. The number of lines completed must be noted on that form at the bottom of the form, in the space provided. DEA Forms 222 for carfentanil, etorphine hydrochloride, and diprenorphine must contain only these substances.

(3) The name and address of the supplier from whom the controlled substances are being ordered must be entered on the form. Only one supplier may be listed on any form.

(4) Each DEA Form 222 must be signed and dated by a person authorized to sign an application for registration or a person granted power of attorney to sign a DEA Form 222 under § 1305.05. The name of the purchaser, if different from the individual signing the DEA Form 222, must also be inserted in the signature space.

(5) Unexecuted DEA Forms 222 may be kept and may be executed at a location other than the registered location printed on the form, provided that all unexecuted forms are delivered promptly to the registered location upon an inspection of the location by any officer authorized to make inspections, or to enforce, any Federal, State, or local law regarding controlled substances.

(c) *Procedure for filling triplicate DEA Forms 222.* As set forth in § 1305.13:

(1) A purchaser must submit Copy 1 and Copy 2 of the triplicate DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files.

(2) A supplier may fill the order, if possible and if the supplier desires to do so, and must record on Copies 1 and 2 the number of commercial or bulk containers furnished on each item and the date on which the containers are shipped to the purchaser. If an order cannot be filled in its entirety, it may be filled in part and the balance supplied by additional shipments within 60 days following the date of the DEA Form 222. No DEA Form 222 is valid more than 60 days after its execution by the purchaser, except as specified in paragraph (c)(6) of this section.

(3) The controlled substances must be shipped only to the purchaser and the location printed by the Administration on the DEA Form 222, except as specified in paragraph (c)(6) of this section.

(4) The supplier must retain Copy 1 of the triplicate DEA Form 222 for his or her files in accordance with paragraph (g)(3) of this section and forward Copy 2 to the Special Agent in Charge of the Drug Enforcement Administration in the area in which the supplier is located. Copy 2 must be forwarded at the close of the month during which the order is filled. If an order is filled by partial shipments, Copy 2 must be forwarded at the close of the month during which the final shipment is made or the 60-day validity period expires.

(5) The purchaser must record on Copy 3 of the triplicate DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser.

(6) DEA triplicate Forms 222 submitted by registered procurement officers of the Defense Supply Center of the Defense Logistics Agency for delivery to armed services establishments within the United States may be shipped to locations other than the location printed on the DEA Form 222, and in partial shipments at different times not to exceed six months from the date of the order, as designated by the procurement officer when submitting the order.

(d) *Procedure for endorsing triplicate DEA Forms 222.* As set forth in § 1305.14:

(1) A triplicate DEA Form 222, made out to any supplier who cannot fill all or a part of the order within the time limitation set forth in paragraph (c) of this section, may be endorsed to another supplier for filling. The endorsement must be made only by the supplier to whom the DEA Form 222 was first made, must state (in the spaces provided on the reverse sides of Copies 1 and 2 of the triplicate DEA Form 222) the name and address of the second supplier, and must be signed by a person authorized to obtain and execute DEA Forms 222 on behalf of the first supplier. The first supplier may not fill any part of an order on an endorsed form. The second supplier may fill the order, if possible and if the supplier desires to do so, in accordance with paragraphs (c)(2) through (4) of this section, including shipping all substances directly to the purchaser.

(2) Distributions made on endorsed DEA Forms 222 must be reported by the second supplier in the same manner as all other distributions.

(e) *Unaccepted and defective triplicate DEA Forms 222.* As set forth in § 1305.15:

(1) A DEA Form 222 must not be filled if either of the following apply:

(i) The order is not complete, legible, or properly prepared, executed, or endorsed.

(ii) The order shows any alteration, erasure, or change of any description.

(2) If a triplicate DEA Form 222 cannot be filled for any reason under this section, the supplier must return Copies 1 and 2 to the purchaser with a statement as to the reason (e.g. illegible or altered).

(3) A supplier may for any reason refuse to accept any order and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph (e).

(4) When a purchaser receives an unaccepted order, Copies 1 and 2 of the triplicate DEA Form 222 and the statement must be attached to Copy 3 and retained in the files of the purchaser in accordance with paragraph (g) of this section. A defective DEA Form 222 may not be corrected; it must be replaced by a new DEA Form 222 for the order to be filled.

(f) *Lost and stolen triplicate DEA Forms 222.* As set forth in § 1305.16:

(1) If a purchaser ascertains that an unfilled triplicate DEA Form 222 has been lost, he or she must execute another in triplicate and attach a statement containing the serial number and date of the lost form, and stating that the goods covered by the first DEA Form 222 were not received through loss of that DEA Form 222. Copy 3 of the second form and a copy of the statement must be retained with Copy 3 of the DEA Form 222 first executed. A copy of the statement must be attached to Copies 1 and 2 of the second DEA Form 222 sent to the supplier. If the first DEA Form 222 is subsequently received by the supplier to whom it was directed, the supplier must mark upon the face "Not accepted" and return Copies 1 and 2 to the purchaser, who must attach it to Copy 3 and the statement. However, if the registrant no longer can use triplicate forms, then the registrant shall proceed by issuing a new single-sheet form in accordance with §1305.16.

(2) Whenever any used or unused DEA Forms 222 are stolen or lost (other than in the course of transmission) by any purchaser or supplier, the purchaser or supplier must immediately upon discovery of the theft or loss, report the theft or loss to the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located, stating the serial number of each form stolen or lost.

(3) If the theft or loss includes any original DEA Forms 222 received from purchasers and the supplier is unable to state the serial numbers of the DEA Forms 222, the supplier must report the date or approximate date of receipt and the names and addresses of the purchasers.

(4) If an entire book of triplicate DEA Forms 222 is lost or stolen, and the purchaser is unable to state the serial numbers of the DEA Forms 222 in the book, the purchaser must report, in lieu of the numbers of the forms contained in the book, the date or approximate date of issuance.

(5) If any unused DEA Form 222 reported stolen or lost is subsequently recovered or found, the Special Agent in Charge of the Drug Enforcement Administration in the Divisional Office responsible for the area in which the registrant is located must immediately be notified.

(g) *Preservation of triplicate DEA Forms 222.* As set forth in § 1305.17:

(1) The purchaser must retain Copy 3 of each executed triplicate DEA Form 222 and all copies of unaccepted or defective forms with each statement attached.

(2) The supplier must retain Copy 1 of each triplicate DEA Form 222 that it has filled.

(3) Triplicate DEA Forms 222 must be maintained separately from all other records of the registrant. DEA Forms 222 are required to be kept available for inspection for a period of two years. If a purchaser has several registered locations, the purchaser must retain Copy 3 of the executed triplicate DEA Form 222 and any attached statements or other related documents (not including unexecuted DEA Forms 222, which may be kept elsewhere under paragraph (b)(5) of this section), at the registered location printed on the DEA Form 222.

(4) The supplier of thiafentanil, carfentanil, etorphine hydrochloride, and diprenorphine must maintain DEA Forms 222 for these substances separately from all other DEA Forms 222 and records required to be maintained by the registrant.

(h) *Return of unused triplicate DEA Forms 222.* As set forth in § 1305.18, if the registration of any purchaser terminates (because the purchaser dies, ceases legal existence, discontinues business or professional practice, or changes the name or address as shown on the purchaser's registration) or is suspended or revoked under §1301.36 of this chapter for all schedule I and II controlled substances for which the purchaser is registered, the purchaser must return all unused triplicate DEA Forms 222 to the nearest office of the Administration.

(i) *Cancellation and voiding of triplicate DEA Forms 222.* As set forth in § 1305.19:

(1) A purchaser may cancel part or all of an order on a triplicate DEA Form 222 by notifying the supplier in writing of the cancellation. The supplier must indicate the cancellation on Copies 1 and 2 of the triplicate DEA Form 222 by drawing a line through the canceled items and printing "canceled" in the space provided for the number of items shipped.

(2) A supplier may void part or all of an order on a triplicate DEA Form 222 by notifying the purchaser in writing of the voiding. The supplier must indicate the voiding in the manner prescribed for cancellation in paragraph (i)(1) of this section.

Dated: February 10, 2019.

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Uttam Dhillon,
Acting Administrator.
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