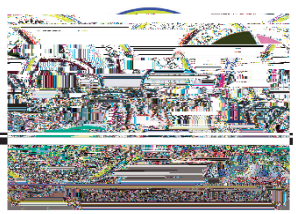
United States Department of Justice
Drug Enforcement Administration
Diversion Control Division

www.DEAdiversion.usdoj.gov



Researcher's Manual

An Informational Outline of the Controlled Substances Act

Revised 2022

Anne Milgram
Administrator
Drug Enforcement Administration

Kristi N. O'Malley
Assistant Administrator
Diversion Control Division

Thomas W. Prevoznik
Deputy Assistant Administrator
Office of Diversion Control Policy

Noreen S. Valentine
Section Chief
Policy Section

Table of Contents

SECTION I - INTRODUCTION

Disclaimer

This Researcher's Manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), U.S.C. 801-904; the Controlled Substances Import and Export Act (CSIEA), 21 U.S.C. 951-971; and DEA regulations, CFR parts 1300 to end. Pertinent citations to the law and regulations are included in this manual.

This Researcher's Manual is a guidance document that provides statutory and regulatory

Message from the Assistant Administrator

The DEA Diversion Control Division is pleased to provide you with the 2022 edition of the Researcher's Manual to assist you in understanding the provisions of the CSA and its implementing regulations. This Researcher's Manual will answer questions you may encounter in your practice and provide guidance in complying with CSA regulations.

There is a legitimate need for conducting research with controlled substances. However, the diversion and abuse of pharmaceutical controlled substances remains a public health concern in the United States. Your role in the proper use of controlled substances in your research helps protect society against drug abuse and diversion. Your compliance with the CSA and its objectives is a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances.

Sincerely,

Kristi N. O'Malley
Assistant Administrator
Diversion Control Division
Drug Enforcement Administration

SECTION II - SCHEDULES OF CONTROLLED SUBSTANCES

Drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in DEA regulations at 21 CFR 1308.11-15. Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States, its relative abuse potential, and likelihood of causing dependence. 21 U.S.C. 812. Some examples of controlled substances in each schedule are listed below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. 21 U.S.C. 812. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use. 21 U.S.C. 812.

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision. 21 U.S.C. 812(b)(1).

Some examples of substances listed in schedule I are heroin, lysergic acid diethylamide, marihuana, peyote, methaqualone, and 3,4-methylenedioxymethamphetamine. 21 U.S.C. 812(c), Schedule I and 21 CFR 1308.11.

Schedule II Controlled Substances

Substances in this schedule have a high potential foligatl us21 U.S. .

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II, have a currently accepted medical use in treatment in the United States, and abuse may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. 812(b)(3).

Examples of schedule III narcotics include morphine combination products containing not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, non-narcotic ingredients in recognized therapeutic amounts, and products containing not more than 90 milligrams of codeine per dosage unit with an equal or greater quantity of an isoquinoline alkaloid of opium (Tylenol with codeine). Also included are buprenorphine products used to treat opioid addiction.

Examples of schedule III non-narcotics include benzphetamine (Didrex), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin). 21 U.S.C. 812 and 21 CFR 1308.13.

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in schedule III, have a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical dependence or psychological dependence relative to substances in schedule III. 21 U.S.C. 812(b)(4).

An example of a schedule IV narcotic is tramadol (Ultram).

Other schedule IV substances include alprazolam (Xanax), carisoprodol (Soma), clonazepam (Klonopin), clorazepate (Tranxene), diazepam (Valium), lorazepam (Ativan), midazolam (Versed), temazepam (Restoril), and triazolam (Halcion). 21 U.S.C. 812(c), Schedule IV, 21 CFR 1308.14.

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV, have a currently accepted medical use in treatment in the United States, and abuse may lead to limited physical dependence or psychological dependence relative to substances in schedule IV. 21 U.S.C. 812(b)(5). They consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitu

SECTION III - REGISTRATION REQUIREMENTS

There are two separate categories for researcher registration which are based on controlled substance schedules, the first is *schedule I researcher*, and the second is *schedule II-V researcher*. If a researcher wishes to conduct research in schedules I and schedules II-V, they must obtain two separate registrations, a researcher may not have schedules I-V on one DEA registration. 21 CFR 1301.13(e).

New Researcher Registration

Unless otherwise exempted, as explained in the subsections below, every researcher who intends to conduct research with schedule I controlled substances or schedule II-V controlled substances must be registered with DEA. 21 U.S.C. 823(f), 21 CFR 1301.11(a). A state license to conduct research and/or a state controlled substance registration, if applicable, must be obtained. 21 U.S.C. 823(f).

To register as a new researcher, the DEA Form 225 must be completed. 21 CFR 1301.13(e)(1)(v), (vi)Unleted.-.0056.2197 T schedule I controlled subst

Registration Application Fee

The annual application fee for a researcher registration is listed on the Application for Registration (DEA Form 225). Instructions for methods of payment and additional information can be found online. If paying by check, make checks payable to "Drug Enforcement Administration."

Application Fee Exemption

Applies to federal, state, and

practitioner consisting of numbers, letters, or a combination thereof as a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12). A current list of internal codes and the corresponding individual practitioners must be kept by the hospital or other institution and made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. 21 CFR 1301.22(c).

• Any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons who is authorized to prescribe, dispense, or administer, but not to procure or purchase, controlled substances in the course of their official duties.

Schedule I Researchers

New Schedule I Researcher Application Addendums

In addition to completing the application itself, a schedule I researcher must file and receive approval for a research protocol. 21 CFR 1301.13(e), 1301.18, 1301.32. An applicant can upload supporting documentation at the time of application. The following "Pre-Application Checklist for Schedule I Researchers" outlines what documents are required:

Pre-Application Checklist for Schedule I Researcher Applications

This checklist is for **new** applicants who intend to handle schedule I controlled substances for research purposes. Additional information on renewing a DEA registration is found towards the end of this chapter.

1.c

a. Activities to satisfy regulatory requirements such as Food and Drug Administration (FDA) submissions or good manufacturing practice;

b. Activities related to production of material used for pilot, scale-up, and reformulation studies; or

c. Activities related to product development including bioavailability, dosage formulation, stability, and validation studies.

For additional questions or clarification related to manufacturing activities please email DPEScheduleIResearch@dea.gov.

2. Registering as a researcher requires a non-refundable fee noted on the application. There is no prorated application fee and the subsequent withdrawal of an application does not qualify for a return of an application fee.

3. The applicant must be the only individual completing and certifying by e-signature that the information provided is accurate for purposes of the DEA application. There is an exception to

iii. Have a protocol.* See 21 CFR 1301.18 and 21 CFR 1301.32 for the protocol requirements. (PDF file upload required).

b. If a schedule I researcher is conducting animal research, the schedule I researcher must:

i. Have approval from Institutional Animal Care and Use Committee (IACUC) for animal studies. (PDF file upload required); and

ii. Have a protocol.* See 21 CFR 1301.18 and 21 CFR 1301.32 for the protocol requirements. (PDF file upload required).

c. If the schedule I research does not use animals or humans (e.g., In-Vitro laboratory research that doesn't require institutional approval, research to develop analytical methods, and research to develop chemical synthesis procedures, etc.) the schedule I researcher must:

i. Have a protocol.* See 21 CFR 1301.18 and 21 CFR 1301.32 for the protocol requirements. (PDF file upload required).

*Protocols: If a given study/project has a consolidated research protocol which covers all of the types of research being performed, then a schedule I researcher only needs to upload the consolidated research protocol once for that study/project. If study/project's research protocols have not been consolidated, then a schedule I researcher must upload a dedicated research protocol for each type of research being performed.

A schedule I researcher must submit a curriculum vitae and research protocol as part of the application process. See 21 CFR 1301.18 and 21 CFR 1301.32 for the protocol requirements. (PDF file upload required).

If schedule I controlled substances mentioned in the research protocol are procured from external sources, then the schedule I researcher must provide the DEA registration number(s) of the source(s) and validate the supplier's name and address.

7. A schedule I researcher may be exempt from the application fee if the applicant is a current direct hire employee for a federal, state, or local government institution, or of a public university. The fee exemption is not applicable for future employment. The exemption will restrict the use of a DEA registration to government or university duties only. In accordance with 21 CFR 1301.21(b), a schedule I researcher must certify their status on the application. A schedule I researcher may forfeit the fee exemption by not complying with this regulation. A schedule I researcher must include an email address that is associated with the fee-exempt location. An applicant can be required to provide evidence of government or public university employment.

8. An applicant should not submit an online application if the applicant mailed a paper application. Duplicate submissions may result in a duplicate collection of non-refundable application fees.

9. For additional questions or clarification, the following services are available:

x

Schedule I Research Protocols

A schedule I research protocol shall contain

The request for a protocol change should be submitted via email to

- Distribute controlled substances in those schedules for which registration was issued to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances, and to persons exempted from registration pursuant to 21 CFR 1301.24 such as law enforcement; and
- Conduct instructional activities with controlled substances.

Note: The manufacture or import of controlled substances authorized by this coincident activity must be for research purposes.

M

- Product development including bioavailability,

If a researcher discontinues business activities either completely or only regarding controlled substances, the researcher must promptly notify the local Special Agent in Charge and seek authority and instructions to dispose of any controlled substances obtained under the authority of that registration. A researcher that discontinues business must return their DEA registration certificate to the local DEA Registration Program Specialist (Appendix F). 21 CFR 1301.52(c).

In the event a state board revokes a researcher's license or registration, DEA will request a voluntary surrender of that DEA registration. If a researcher surrenders their DEA registration for cause, it shall be terminated when a duly executed DEA Form 104, Voluntary Surrender of Controlled Substances Privileges, or any signed writing indicating a desire to surrender a registration is received by any DEA employee. 21 CFR 1301.52(a). If a researcher refuses to surrender their registration, DEA will pursue administrative action to revoke the DEA registration based on lack of state authorization. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

Unwanted controlled substances in the researcher's possession must be disposed of in accordance with DEA regulations (See *Section VIII, Disposal of Controlled Substances*).

Denial, Suspension, or Revocation of Registration

Under 21 U.S.C. 824(a), DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that a researcher has does any of the following:

1. Materially falsified the application.
2. Been convicted of a felony relating to a controlled substance or a List I chemical.
3. Had a state license or registration suspended, revoked, or denied by a competent state authority and is no longer authorized by state law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals, or has had a suspension, revocation, or denial of a registration recommended by a competent state authority.
4. Committed an act which would render the DEA registration inconsistent with the public interest.
5. Been excluded (or directed to be excluded) from participation in a Medicare or state health care program.

Denial of Registration in the Public Interest

In determining the public interest, 21 U.S.C. 823(f) provides that the following factors are to be considered:

1. The recommendation of the appropriate state licensing board or professional disciplinary authority.
2. A researcher's experience in dispensing or conducting research with respect to controlled substances.
3. A researcher's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
4. Compliance with applicable state, federal, or local laws relating to controlled substances.

DEA Forms 222 have an order form number and are 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 DEA

executed DEA Forms 222 if applicable, and must be available for inspection. 21 CFR 1305.05(a). The power of attorney is not submitted to DEA.

Suggested formats for granting and revoking a power of attorney foll18ge 28 of2R 1305.05(a

Notice of Revocation

Cancellation and Voiding DEA Forms 222

A purchaser may cancel part or all of an order on a DEA Form 222 by notifying the supplier in writing of the cancellation. 21 CFR 1305.19(a). 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. 21 CFR 1305.19(a).

A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing of the voiding. 21 CFR 1305.19(b). The supplier must indicate the voiding on the original DEA Form 222 sent by the purchaser by drawing a line through the canceled items and printing "voided" in the space provided for the number of items shipped. 21 CFR 1305.19(b).

For information regarding canceled electronic orders, see below, *CSOS - Electronic Order Forms*.

Lost or Stolen DEA Forms 222

If a purchaser ascertains that an unfilled DEA Form 222 has been lost, the purchaser 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. 21 CFR 1305.16(a). 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. 21 CFR 1305.16(a). A copy of the statement must be attached to a copy of the second DEA Form 222 sent to the supplier. 21 CFR 1305.16(a). 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. 21 CFR 1305.16(a).

A researcher, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss or theft to the local DEA Diversion Field Office (Appendix F) and provide the serial numbers of each lost or stolen order form. 21 CFR 1305.16(b).

If any DEA Forms 222 are lost or stolen, and the purchaser is unable to provide the order form numbers of DEA Forms 222, the purchaser must report, in lieu of numbers of the forms, the date or

Controlled Substance Ordering System (CSOS) – ElectronicOrderirre

requested. Test materials may consist of active ingredient dosage units, placebo, or some combination thereof. The registrant will not know if the test materials received actually contain a controlled substance until the end of the study.

2. The controlled substance s

"cannabis," "cannabis plant," and "cannabis resin"–all of which are generally encompassed by the CSA definitions of "marihuana" in 21 U.S.C. 802(16). Therefore, for purposes of this manual, the terms "cannabis" and "marihuana" are interchangeable.

As of January 19, 2021, the effective date of the final rule, and in compliance with the CSA and the Single Convention, DEA has the exclusive right of importing, exporting, wholesale trading, and maintaining cannabis stocks other than those held by registered manufacturers of medicinal cannabis or cannabis preparations. "Medicinal cannabis" means a drug product made from the cannabis plant, or derivatives thereof that can be legally marketed under the Federal Food, Drug, and Cosmetic Act. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana. "Cannabis preparation" means cannabis that was delivered to DEA and subsequently converted by a registered manufacturer into a mixture (solid or liquid) containing cannabis, cannabis resin, or extracts of cannabis. However, such term does not include any material, compound, mixture, or preparation that falls outside the CSA definition of marihuana.

Over the last several decades, the National Institute on Drug Abuse (NIDA), a component of the National Institutes of Health (NIH), has administered a contract to produce high quality marihuana for use by researchers who had obtained federal funding (grants) for such research. This contract was awarded to the National Center for Natural Products Research at the University of Mississippi (National Center). The National Center was the sole DEA registrant in the United States authorized to grow marihuana for the purposes of supplying researchers. The National Center was authorized to grow marihuana up to the limit established by their DEA-issued quota. At the time of harvest, some of the material was held in in inventory at the National Center, while some of it was distributed to another DEA registrant, Research Triangle Institute (RTI). At the direction of NIDA, via NIDA's Drug Supply Program (DSP), the National Center and RTI prepared marihuana in a manner suitable for research studies and then shipped it to researchers. Marihuana held in inventory at the National Center was the property of NIDA.

The final rule has instituted changes to the scheme described above. Although NIDA can and will continue to administer the contract in support of its DSP, and the National Center (or other NIDA contract holder) can continue to grow and produce marihuana in support of research pursuant to that contract, the marihuana grown at the National Center will not be the property of NIDA, as was previously the case, rather, DEA takes title and possession of the crop, and the material is maintained, under seal, at the National Center until such time distribution to another DEA registrant is authorized.

Under the new regulations contained within the final rule, there are changes related to the availability of cannabis for research and to DEA's role in all transactions involving cannabis, to comply with DEA's statutory and treaty obligations. As previously stated, effective January 19, 2021, DEA has the exclusive right of importing, exporting, wholesale trading, and maintaining stocks of cannabis, other than those held by registered manufacturers and distributors of medicinal cannabis or cannabis preparations.

DEA reviews pending bulk manufacturers of marihuana with the goal of approving multiple bulk manufacturers so as to increase the number and variety of cannabis growers in order to diversify the

supply available to researchers. The number of manufacturers approved by DEA is limited, as required by the CSA, to the number necessary to produce an adequate and uninterrupted supply under adequately competitive conditions. 21 U.S.C. 823(a)(1). All registered manufacturers who cultivate cannabis are required to transfer ownership of their total crops of cannabis to DEA. DEA purchases the cannabis grown by DEA-registered manufacturers and subsequently sells the marihuana to DEA registrants who seek to acquire it for research, product development, or other lawful purposes under the CSA.

Although DEA takes title to the cannabis from DEA registered manufacturers, and sells it to researchers, the price of the cannabis is negotiated between the grower and the purchaser. In addition to the negotiated price, DEA includes an administrative fee (per kilogram) which is added on to the sales price of the marihuana it sells to researchers. The purpose of the administrative fee is to ensure the full recovery by DEA of

Ordering Schedules III-V Controlled Substances

The researcher must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. 21 CFR 1304.21(a), (d). Pursuant to 21 CFR 1304.22(a)(2) and (c), such receipts must also contain the following information:

1. The name of the substance;

2. Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

3. The number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from whom the units were acquired;

4. The number of commercial containers distributed to other persons, including the date of and number of containers in each reduction from inventory, and the name, address, and registration number of the person to whom the containers were distributed; and

5. The number of units of finished forms and/or commercial containers distributed or disposed of in any other manner by the registrant (e.g., by distribution of complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, and registration number of the person to whom distributed, and the quantity in finished form distributed or disposed.

In addition, these receipts must be maintained either separately from all other records of the registrant or in such form that the information required is readily retrievable from the ordinary business records of the registrant. 21 CFR 1304.04(f)(2).

SECTION V – RECORDKEEPING REQUIREMENTS

Researchers must maintain complete and accurate records on a current basis for each controlled substance manufactured, imported, purchased, received, stored, delivered, distributed, dispensed, or otherwise disposed of. 21 CFR 1304.21(a). These records are required to provide accountability of all controlled substances to help reduce the potential for diversion.

DEA requires that all records concerning controlled substances be maintained for at least two years, in a readily retrievable manner, for inspection and copying by duly authorized DEA officials. 21 CFR 1304.04(a), 1316.02(c), 21 U.S.C. 827(b).

Pursuant to 21 CFR. 1300.01(b), readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or

2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Required Records

The controlled substance records researchers must maintain are:

- Executed official order forms (DEA Form 222) or the electronic equivalent.
- Unexecuted official order forms (DEA Form 222).
- Power of Attorney authorization to sign order forms, if applicable.
- Receipts and/or invoices for schedules III, IV, and V 0 TD(e)Tj.5601 0fn .a468.54r i.261 T 612 -791.97

es f

dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser. 21 CFR 1304.22(c).

SECTION VI – INVENTORY REQUIREMENTS

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule I-V controlled substances. The CSA requires that all inventory records be maintained at the registered location for at least two years for copying and inspection. 21 CFR 1304.04(a), 21 U.S.C. 827(b). In addition, the inventory records of schedule I and II controlled substances must be kept separate from all other records of the researcher. 21 CFR. 1304.04(g). The inventory records of schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the researcher or in such form that the information required is readily retrievable from ordinary business records of the researcher. 21 CFR 1304.04(g).

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. 21 U.S.C. 827(a)(1); 21 CFR 1304.11(b). In the event there are no stocks of controlled substances on hand, when the registrant commences business, the registrant should make a record showing a zero inventory. 21 CFR 1304.11(b). There is no requirement to submit a copy of the inventory to DEA. Pursuant to 21 CFR 1304.11(a), (b) and (e)(6), the inventory shall include:

1. The date of the inventory.
2. Whether the inventory was taken at the beginning or close of business.
3. The name of each controlled substance inventoried.
4. The finished form of each of the substances (e.g., 10 milligram tablet).
5. The number of dosage units or volume of each finished form in the commercial container (e.g., 100 tablet bottle or 3 milliliter vial).
6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles).
7. The total count of the substance.
8. For damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compounding, the inventories shall include the name of the substance, the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form, and the reason for the

substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

DEA recommends, but does not require, an inventory record that includes the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

Biennial Inventory

After the initial inventory, the registrant is required to take a new inventory at least every two years, which requires the same information as the initial inventory (see list above) of all controlled substances on hand. 21 CFR 1304.11(c). There is no requirement to submit a copy of the inventory to DEA.

Newly Scheduled Controlled Substance Inventory

When a drug not previously listed as a controlled substance is scheduled, the drug must be inventoried as of the effective date of scheduling, if possessed by the registrant. 21 CFR 1304.11(d).

inspection as part of the registration approval process. If a controlled substance storage receptacle does not meet the security standards listed above, it may delay the processing new applications.

Controlled Subst

If completing the paper version, the researcher s

3. Contact the local DEA Diversion Field Office to request assistance to dispose of the controlled substances pursuant to 21 CFR 1317.05(a)(4).

A record of the destruction should be kept pursuant to 21 CFR 1304.21(e).

If the breakage or spillage is clearly observed, but the controlled substances are not recoverable, the registrant should document the circumstances of the event in their records. It is DEA's position that, in order to maintain complete and accurate records in accordance with 21 CFR 1304.21(a), non-recoverable breakage or spillage must be recorded on a DEA Form 41 and, as with any other form of disposal under 21 CFR part 1317, must be signed by two individuals who can testify that a breakage or spillage occurred. These records must be maintained in the registrant's files and contain such information as required by 21 CFR 1304.22(c).

under the law of the state in which they desire to do such act, nor shall compliance with such parts be construed as compliance with other federal or state laws unless expressly provided in such other laws. 21 CFR 1307.02.

Reverse Distributors Authorized to Dispose of Controlled Substances

A researcher may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. 21 CFR 1317.05(a)(2). When a researcher transfers schedule I or II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the researcher. 21 CFR 1305.03, 1317.10(b). When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the researcher must maintain a record of distribution that lists the drug name, dosage form, drug strength, quantity, and date transferred. 21 CFR 1317.10(a), 1304.22(a)(2)(iv). A DEA-registered reverse distributor who destroys the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to DEA when the controlled substances have been destroyed. 21 CFR 1304.21(e). A DEA Form 41 should not be used to record the transfer of controlled substances between the researcher and the reverse distributor disposing of the drugs.

A paper version of the DEA Form 41 can be requested by writing to:

Drug Enforcement Administration
Diversion Control Division
Attn: Registration & Program Support Section/DRR
P.O. Box 2639
Springfield, VA 22152-2639

Appendices

APPENDIX A – List of Abbreviations

CFR	Code of Federal Regulations
CSA	Controlled Substances Act
CSOS	Controlled Substances Ordering System
DEA	Drug Enforcement Administration
DRR	DEA Headquarters Registration Section
FDA	Food and Drug Administration
IND	Investigational New Drug
NIDA	National Institute on Drug Abuse
NIH	National Institutes of Health
U.S.	United States
U.S.C.	United States Code

APPENDIX B – Guidelines for Completing the DEA-Form 106

Instructions for completing the DEA Form 106 are provided when filling out either the hard copy or the electronic version of the form. Listed below are additional guidelines:

- Do not use a DEA Form 106 to report an accidental spillage. Save the broken bottles, salvage the product if possible, and contact your local DEA Diversion Field Office for additional instructions.

- Do not use a DEA Form 106 to report miscounts or adjustments to inventory involving clerical errors. A separate log documenting the discrepancies may be kept at the researcher's discretion.

The following guidelines apply only if you are using the hard copy version of the DEA Form 106:

- If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 the date of the theft or loss (or first discovery of theft or loss). Provide estimated beginning and ending dates of the thefts in the comment section with an explanation.

- On the next line, enter the number of thefts or losses experienced in the last 24 months, but do not include the current theft or loss being reported. If the current theft or loss was the only theft or loss in the last 24 months, enter "0" (zero).

- In section five, enter the amount paid for the controlled substances.

- In section three, if you accepted receipt of the controlled substance(s) before discovering a loss in transit, identify the supplier and its DEA registration number.

- When explaining how many losses occurred from the same carrier, do not include the current loss.

- The date next to the signature and title on page 4 should be the date the form was completed and transmitted to DEA.

- If amending a paper version of a prior DEA Form 106, print **Amended** in the upper front page margin, with the date of the theft.

APPENDIX C – Internet Resources

DEA's Diversion Control Division Website - www.DEAdiversion.usdoj.gov

DEA Homepage - www.dea.gov

DEA E-Commerce Program (CSOS) website – www.deaecom.gov

U.S. Government Printing Office/Code of Federal Regulations – www.fdsys.gov

Provides access to the CFR, Parts 1300 to End, primary source for the Researcher's Manual, and the Federal Register which contains proposed and finalized amendments to the CFR.

Office of National Drug Control Policy (ONDCP) - www.whitehousedrugpolicy.gov

Food and Drug Administration - www.FDA.gov

National Association of State Controlled Substances Authorities - www.nascsa.org

APPENDIX D – Small Business and Agriculture Regulatory Enforcement

APPENDIX E – Additional Assistance and Plain Language

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the CSA and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding DEA's requirements or regulatory activities, please contact your local DEA Diversion Field Office. Every effort will be made to respond promptly to your inquiry.

Plain Language

DEA has made every effort to write this Researcher's Manual in clear, plain language. If you have suggestions as to how to improve the clarity of this Researcher's Manual, please contact us at:

Drug Enforcement Administration
Attn: Policy Section/DPY
8701 Morrissette Drive
Springfield, VA 22152
Telephone: (571) 362-3260

APPENDIX F – DEA Office Locator

Drug Enforcement Administration
Diversion Field Office Locations

Visit www.DEAdiversion.usdoj.gov for current addresses and telephone numbers.

Diversion Field Registration Specialists

To locate your local DEA Diversion Field Registration Specialist, open the hyperlink below by right-clicking on the hyperlink, and then select "Open Hyperlink." Then, in the appropriate search box, enter the zip code, or in the alternative, the city or county and the state, then press "Enter" on your keyboard.

https://www.deadiversion.usdoj.gov/contactDea/spring/fullSearch