

## Environmental Health and Safety

### Standard Operating Procedure (SOP) for the Disposal of Controlled Substances

#### I Purpose

This SOP establishes procedures for the collection and destruction of discarded United States Drug Enforcement Administration (USDEA or DEA) controlled substances (CS) at Iowa State University (ISU).

#### II Scope

This SOP applies to the collection and disposal of CS in the following situations:

1. Discarded substances purchased prior to regulation by the DEA but now defined as controlled substances.
2. Discarded reagent chemicals defined as controlled substances.
3. Abandoned (orphaned) controlled substances where the original authorized user cannot be identified.
4. Controlled substances designated for discard by other University DEA registrants unable to perform witnessed destruction of the materials or return them to a reverse distributor.

ISU Police will assume control of the materials described in items 1-3 per standard evidence collection procedures. Researchers with individual DEA registration numbers offering controlled substances for disposal (situation 4) will complete the appropriate chain of custody forms. EH&S will coordinate the collection of these controlled substances by ISU Police.

This SOP does not apply to controlled substances distributed, destroyed, or remitted to a reverse distributor by the Veterinary Medicine Pharmacy, Thielen Student Health Pharmacy, or other DEA licensed ISU faculty and staff. Individual DEA registrants are responsible for following all DEA and State of Iowa requirements, internal SOPs, and procedures prescribed by EH&S and ISU Purchasing Department for the use and purchasing of controlled substances.

#### III Regulations

- 21 Code of Federal Regulations Parts 1300–1399 (Drug Manufacturing, Distribution, Control, and Disposal)
- Iowa Administrative Code Part 657 (Pharmacy Examiners Board)
- 40 Code of Federal Regulations Parts 261, 262, 264-266, 268, 270 & 273 [Environmental Protection Agency- Resource Conservation and Recovery Act (EPA-RCRA)]

#### **IV US DEA Controlled Substance Registration**

The USDEA limits the manufacture, distribution, use, storage, and disposal of chemicals classified as controlled substances. Controlled substances are defined in five Schedules, Schedule 1 being the most restrictive. Possessors of controlled substances must be registered with the USDEA. Iowa State University is registered with the USDEA through the Purchasing Department, Vet Pharmacy, Thielen Student Health Pharmacy, and various researchers. Police agencies are not required to be registered with the USDEA for purposes of controlled substance handling or disposal. As defined in this SOP, ISU Police is functioning as a destroyer of controlled substances for ISU.

#### **V Authorized Personnel**

In order to prevent unauthorized possession, use, or sale of controlled substances, only ISU Police personnel are authorized to collect, transport, store, and destroy controlled substances as outlined in Section II. ISU Police personnel are State of Iowa employees and have passed comprehensive background checks.

#### **VI Determination of Controlled Substances**

Controlled substances will be determined by reviewing the schedules of controlled substances at:

- <http://www.deadiversion.usdoj.gov/schedules/>

and the list of Exempted Materials at:

- <http://www.deadiversion.usdoj.gov/schedules/#exempt>

Only non-exempt, Schedule 1-5 controlled substances must be handled as outlined in this SOP. Exempt items will be handled as non-regulated chemical waste by EH&S.

The Management Standards for Hazardous Waste Pharmaceuticals Rule has eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA CS. EPA now defers to DEA regulation. See link to the Final Rule below:

- [https://www.deadiversion.usdoj.gov/mtgs/pract\\_awareness/resources/EPA\\_Haz\\_Waste\\_Pharmaceuticals.pdf#search=dual%20regulation](https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/resources/EPA_Haz_Waste_Pharmaceuticals.pdf#search=dual%20regulation)

## Collection and Tracking of Controlled Substances

- VII EH&S will attempt to identify the DEA authorized registrant of all discarded controlled substances. If the registrant can be identified they will be instructed in proper storage and disposal requirements. ISU Police will only accept controlled substances for which the original user cannot be identified, or if the authorized registrant cannot destroy or return the material to a reverse distributor.

EH&S will call the main police dispatch at 294-4428 on the morning of the planned incineration date to coordinate an ISU collection of controlled substances. EH&S personnel will accompany ISU Police to the location of the controlled substances.

If the controlled substances are located at the Veterinary Medicine College EH&S will contact the College of Veterinary Medicine Liaison directly at 294-1616 or 515-259-0929.

EH&S will also coordinate with whomever is currently in control of “orphaned” controlled substances to schedule a time for ISU Police to take possession. The Point of Contact for the “orphaned” controlled substances will fill out Block B of the DEA Form 41 for “Orphaned” controlled substances.

The Registrant will fill out Blocks A and B on the DEA Form 41 for “Registrant” controlled substances.

ISU Police Dispatch will assign an event number when ISU Police accepts any controlled substances. The event number will be recorded at the top of the DEA Form 41.

The DEA Form 41 and the incineration log will serve as verification of destruction of the CS and will be retained as required by state and federal regulation.

See attached Flow Diagram for Registrant and Orphaned CS.

### **See CS Disposal Categories Below:**

- I. CS in registrant inventory→
  - a) First-registrant should contact distributor where drugs were purchased and determine if they can return CS for credit (reverse distribution).
  - b) If reverse distribution isn't an option the registrant can begin destruction process by completing “Registrant” DEA Form 41 (blocks A & B), and contacting EH&S to begin coordination with ISU Police.
  - c) “Registrant” DEA Form 41 is attached to this email.
  
- II. Expired CS in a registrant's inventory→
  - a) First-registrant should contact distributor where drugs were purchased and determine if they can return CS for credit (reverse distribution).

- b) If reverse distribution isn't an option the registrant can begin destruction process by completing "Registrant" DEA Form 41 (blocks A & B), and contacting EH&S to begin coordination with ISU Police.
- c) "Registrant" DEA Form 41 is attached to this email.

III. Expired CS not in a registrant's inventory→

- a. CS are documented on an "Orphaned" DEA form 41, EH&S coordinates with ISU Police to take possession of CS, ISU Police drives CS to incinerator where ISU Police, and EH&S incinerator operator witness destruction by incineration, and sign as witnesses on "Orphaned" DEA Form 41.
- b. "Orphaned" DEA Form 41 is available upon request.

IV. "Orphaned" CS→

- a) CS are documented on an "Orphaned" DEA form 41, EH&S coordinates with ISU Police to take possession of CS, ISU Police drive CS to incinerator where ISU Police, and EH&S incinerator operator witness destruction by incineration, and sign as witnesses on "Orphaned" DEA Form 41.
- b) "Orphaned" DEA Form 41 is available upon request.

## VIII Security

Controlled substances will only be collected and transported by ISU Police. Controlled substances will be transported directly to the Veterinary Medicine Incinerator (VMI) for immediate destruction or in the event of an emergency stored in a secure locker at the ISU Police Office. Access to evidence storage facilities at the ISU Police Office is restricted at all times to authorized personnel.

## IX Disposal

ISU Police will witness the destruction of controlled substances at VMI. The incinerator is operated by state-licensed ISU personnel. The incinerator operates at temperatures in excess of 1500 degrees Fahrenheit. Destruction of materials can be witnessed through a burn chamber viewing port.

Destroyed controlled substances will be tracked by EH&S staff on a "Registrant" DEA Form 41, or an "Orphaned" DEA Form 41.

EH&S will keep a paper copy of controlled substances destroyed on DEA Form 41 on file for the duration required by state and federal regulations.

ISU Police and the Registrant, or Registrant Designee will sign the "Registrant" DEA Form 41 as witnesses to destruction and write the event number assigned to that particular disposal date on the form.

ISU Police and the EH&S Incinerator Operator will sign the “Orphaned” DEA Form 41 as witnesses to destruction and write the event number assigned to that particular disposal date on the form.

ISU Police will not need a copy of the DEA Form 41 as they will track the destruction of each controlled substance through their event number.

Reviewed and Approved

Signature \_\_\_\_\_ Date \_\_\_\_\_

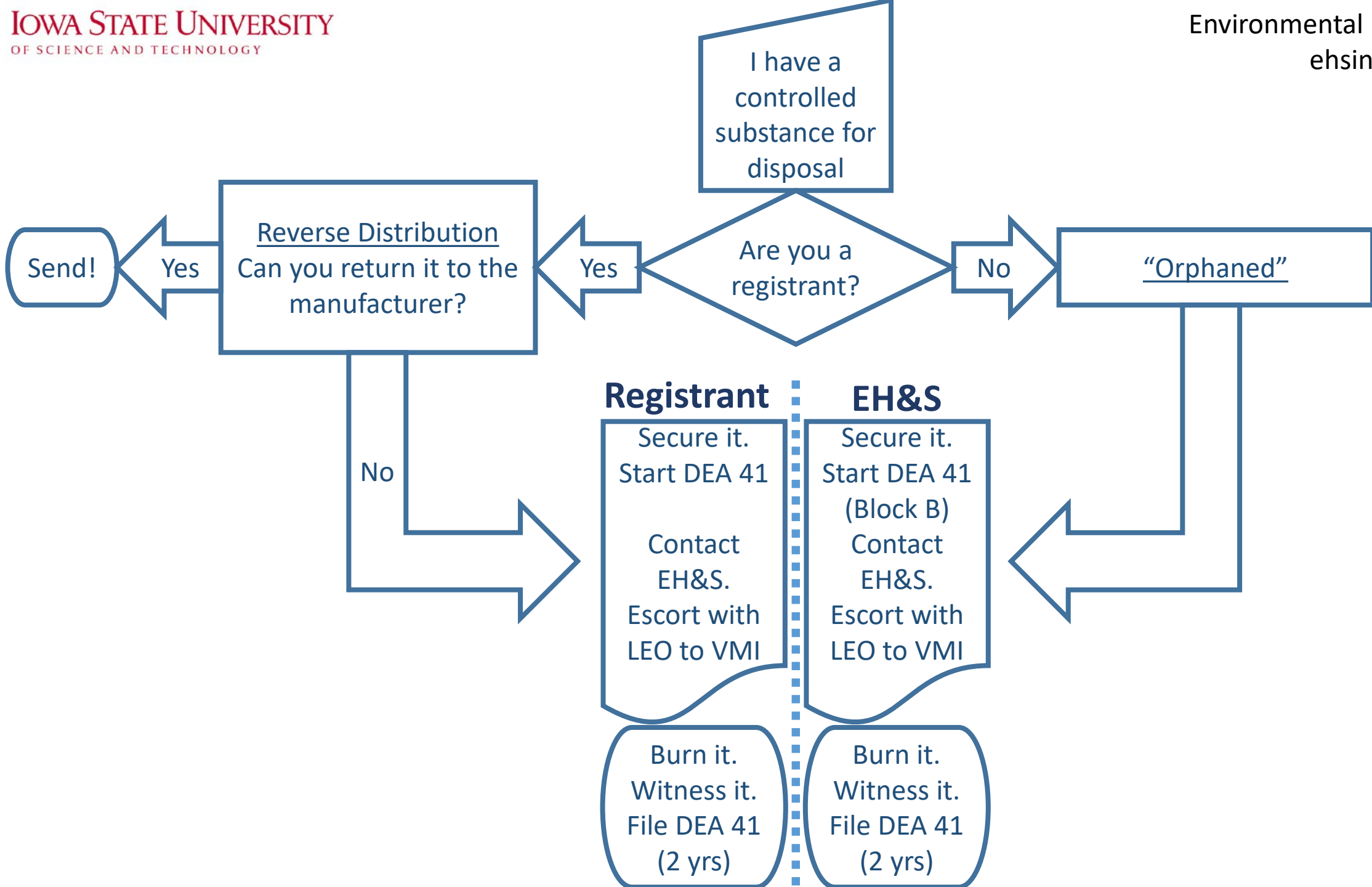
Print Name \_\_\_\_\_ Program Manager, EH&S

Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ Director, EH&S

Signature \_\_\_\_\_ Date \_\_\_\_\_

Print Name \_\_\_\_\_ ISU Police



I have a controlled substance for disposal

Are you a registrant?

Orphaned

Reverse Distribution  
Can you return it to the manufacturer?

Send!

**Registrant**

Secure it.  
Start DEA 41  
  
Contact EH&S.  
Escort with LEO to VMI

Burn it.  
Witness it.  
File DEA 41 (2 yrs)

**EH&S**

Secure it.  
Start DEA 41 (Block B)  
Contact EH&S.  
Escort with LEO to VMI

Burn it.  
Witness it.  
File DEA 41 (2 yrs)

No

Yes

No

Yes

**U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION  
REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED  
FORM DEA-41**

**A. REGISTRANT INFORMATION**

Registered Name:	DEA Registration Number:	
Registered Address:		
City:	State:	Zip Code:
Telephone Number:	Contact Name:	

**B. ITEM DESTROYED**

**1. Inventory**

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
<i>Examples</i>	<i>16590-598-60</i>	<i>N/A</i>	<i>Kadian</i>	<i>60mg</i>	<i>Capsules</i>	<i>60</i>	<i>2</i>	<i>0</i>	<i>120 Capsules</i>
	<i>0555-0767-02</i>	<i>N/A</i>	<i>Adderall</i>	<i>5mg</i>	<i>Tablet</i>	<i>100</i>	<i>0</i>	<i>83</i>	<i>83 Tablets</i>
	<i>9050</i>	<i>B02120312</i>	<i>Codeine</i>	<i>N/A</i>	<i>Bulk</i>	<i>1.25 kg</i>	<i>N/A</i>	<i>N/A</i>	<i>1.25 kg</i>
1.									
2.									
3.									
4.									
5.									
6.									
7.									

**2. Collected Substances**

	Returned Mail-Back Package	Sealed Inner Liner	Unique Identification Number	Size of Sealed Inner Liner	Quantity of Packages(s)/Liner(s) Destroyed
<i>Examples</i>	<i>X</i>		<i>MBP1106, MBP1108 - MBP1110, MBP112</i>	<i>N/A</i>	<i>5</i>
		<i>X</i>	<i>CRL1007 - CRL1027</i>	<i>15 gallon</i>	<i>21</i>
		<i>X</i>	<i>CRL1201</i>	<i>5 gallon</i>	<i>1</i>
1.					
2.					
3.					
4.					
5.					
6.					
7.					

**C. METHOD OF DESTRUCTION**

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

**D. WITNESSES**

**I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.**

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

**E. INSTRUCTIONS**

- Section A. REGISTRANT INFORMATION:** The registrant destroying the controlled substance(s) shall provide their DEA registration number and the name and address indicated on their valid DEA registration, in addition to a current telephone number and a contact name, if different from the name on the valid DEA registration.
- Section B. (1) Inventory:** This part shall be used by registrants destroying lawfully possessed controlled substances, other than those described in Section B(2). In each row, indicate the National Drug Code (NDC) for the controlled substance destroyed, or if the substance has no NDC, indicate the DEA Controlled Substances Code Number for the substance; if the substance destroyed is in bulk form, indicate the batch number, if available. In each row, indicate the name, strength, and form of the controlled substance destroyed, and the number of capsules, tablets, etc., that are in a full package (pkg. qty.). If destroying the full quantity of the controlled substance, indicate the number of packages destroyed (number of full pkgs.). If destroying a partial package, indicate the partial count of the capsules, tablets, etc. destroyed (partial pkg. count). If destroying a controlled substance in bulk form, indicate that the substance is in bulk form (form) and the weight of the substance destroyed (pkg. qty.). In each row, indicate the total number of each controlled substance destroyed (total destroyed).
- Section B. (2) Collected Substances:** This part shall be used by registrants destroying controlled substances obtained through an authorized collection activity in accordance with 21 U.S.C. 822(g). In each row, indicate whether registrant is destroying a mail-back package or an inner liner. If destroying a mail-back package, enter each unique identification number separated by a comma and/or as a list in a sequential range and total quantity of packages being destroyed. If destroying an inner liner, enter each unique identification number separated by a comma and/or as a list in a sequential range based on the size of the liners destroyed and the total quantity of inner liners being destroyed. In the case of mail-back packages or inner liners received from a law enforcement agency which do not have a unique identification number or clearly marked size, include the name of the law enforcement agency and, if known, the size of the inner liner or package. **DO NOT OPEN ANY MAIL-BACK PACKAGE OR INNER LINER; AN INVENTORY OF THE CONTENTS OF THE PACKAGES OR LINERS IS PROHIBITED BY LAW AND IS NOT REQUIRED BY THIS FORM.**
- If additional space is needed for items destroyed in Section B, attach to this form additional page(s) containing the requested information for each controlled substance destroyed.
- Section C. METHOD OF DESTRUCTION:** Provide the date, location, and method of destruction. The method of destruction must render the controlled substance to a state of non-retrievable and meet all applicable destruction requirements.
- Section D. WITNESSES:** Two authorized employees must declare by signature, under penalty of perjury, that such employees personally witnessed the destruction of the controlled substances listed in Section B in the manner described in Section C.
- You are not required to submit this form to DEA, unless requested to do so. This form must be kept as a record of destruction and be available by the registrant for at least two years in accordance with 21 U.S.C. 827.

**Paperwork Reduction Act Statement:** The information collected on this form is necessary for DEA registrants to record controlled substances destroyed in accordance with the Controlled Substances Act (CSA). The records that DEA registrants maintain in accordance with the CSA must be kept and be available, for at least two years, for inspection and copying by officers or employees of the United States authorized by the Attorney General. 21 U.S.C. 827. DEA estimates that it will take approximately 30 minutes to complete this form, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. The completion of this form by DEA registrants that destroy controlled substances is mandatory in accordance with 21 U.S.C. 827. Please note that an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Comments regarding this information collection, including suggestions for reducing the burden estimate, should be directed to the Drug Enforcement Administration, DEA Federal Register Representative/ODL, 8701 Morrisette Drive, Springfield, Virginia 22152.



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**A. REGISTRANT INFORMATION**

Registered Name:	DEA Registration Number:	
Registered Address:		
City:	State:	Zip Code:
Telephone Number:	Contact Name:	

**B. ITEM DESTROYED**

**1. Inventory**

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1.					
2.					
3.					
4.					
5.					
6.					
7.					

**C. METHOD OF DESTRUCTION**

Date of Destruction:	Method of Destruction:	
Location or Business Name:		
Address:		
City:	State:	Zip Code:

**D. WITNESSES**

**I declare under penalty of perjury, pursuant to 18 U.S.C. 1001, that I personally witnessed the destruction of the above-described controlled substances to a non-retrievable state and that all of the above is true and correct.**

Printed name of first authorized employee witness:	Signature of first witness:	Date:
Printed name of second authorized employee witness:	Signature of second witness:	Date:

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