

Controlled Substances SOP 07: DEA 222 Forms Management and Use**1. Purpose**

This procedure covers the handling of DEA 222 forms used in procuring or disposing of Schedule II controlled substances at Caltech.

2. Regulatory References

21 CFR 1305

3. Training Requirements

All Controlled Substances SOP.

4. General Information**A. Abbreviations:**

- 1) Controlled Substance (CS)
- 2) Institute Point of Contact, Director of Research Compliance (IPOC)
- 3) Central Controlled Substances Custodian (CCSC)
- 4) Laboratory Controlled Substances Custodian (LCSC)
- 5) Principal Investigator (PI)
- 6) Authorized Person (AP)
- 7) Controlled Substances Tracking System (CST)
- 8) Office of Laboratory Animal Resources (OLAR)
- 9) Office of Research Compliance (ORC)
- 10) Environmental Health and Safety (EHS)
- 11) Employee and Organizational Development (EOD)
- 12) Unified Distribution, Transfer, and Disposal Form (UDTD)

B. Caltech has two DEA licenses, one managed by EHS and one managed by OLAR. Each license has its own CCSC, who is responsible for Implementing this SOP, as described.

5. Procedure

The DEA is transitioning from a triplicate DEA Form 222 to a single sheet form. The procedures described below delineate differences between the use of the single vs. triplicate forms. After October 30, 2021, triplicate forms will no longer be accepted.

A. Ordering of DEA 222 Forms

- 1) Each CCSC must request DEA 222 forms from the IPOC. Please note the fulfillment of orders can take between 2-4 weeks.
- 2) The IPOC will order DEA 222 Forms for each specific license, as requested by the CCSC, through the secured DEA website. The DEA222 Forms will be delivered directly to the requesting CCSC.

B. Receipt and Recording of DEA 222 Forms

- 1) Upon receipt of the DEA 222 Forms, the CCSC shall enter the DEA 222 serial numbers into the designated CCSC DEA 222 Excel file (see sample below), including the date of receipt.

The CCSC shall highlight the new entries using a reference color that indicates that these serial numbers are new and unused. For example:

OLAR DEA 222 Forms Tracking				
DEA 222 Form #	Date Forms Received	Date Used	Substances Listed	
190684041	~11/2018	3/11/2019	Sufentanil Citrate	
190684042	~11/2018	3/11/2019	VOIDED	
190684043	~11/2018	3/25/2019	Fentanyl	
190684044	~11/2018	7/1/2019	Morphine Sulfate, Fentanyl Citrate	
190684045	~11/2018	7/24/2019	Morphine Sulfate	
190684046	~11/2018	8/16/2019	Morphine	
192868510	~2/2019			
192868511	~2/2019			
192868512	~2/2019			
192868513	~2/2019			
192868514	~2/2019			
192868515	~2/2019			
192868516	~2/2019			

- 2) The CCSC shall then store the DEA 222 Forms in a designated secure location, for future use.
- 3) If a supplier rejects the order and returns a DEA222 Form, Copies 1 and 2 of the triplicate form or the original DEA222 Form for a single form must be attached to Copy 3 or the Copy of the original DEA222 Form, and retained in accordance with our records retention requirements.

C. Preparing a DEA 222 Form for Purchase

- 1) When a laboratory initiates a purchase of a Schedule II CS for research use, the CCSC will prepare a DEA222 Form, and must complete an additional step in the Techmart approval process.
- 2) In Techmart, the CCSC will include the following note in the “Supplier’s Instructions”:

“DEA 222 Form required for this material. Please contact [yourCCSCemail]@caltech.edu to secure form.”


Internal Info	
Note to Buyer	They may contact you about a DEA 222 form for this item. Please route that request to me.
LCSC Contact Name/Ext.	Bin Yang / x6862
IACUC Protocol #/Authorization #	1650
Internal Attachments	
External Info	
Supplier Instructions	A DEA 222 form will be required for this material. Please contact mchuah@caltech.edu to secure the form. *** NOTIFY mchuah@caltech.edu WITH THE FEDEX TRACKING NUMBER AFTER SHIPMENT PICKUP BY FEDEX ***
External Attachments	
Total 74.5	

3) The CCSC will complete the DEA 222 Form as follows:

Sample DEA Form 222

See Reverse of PURCHASER'S Copy for Instructions		No order form may be issued for Schedule I and II substances unless a completed application form has been received. (21 CFR 1305.04).		OMB APPROVAL No. 1117-0010		
TO: (Name of Supplier) ZOOPHARM A			STREET ADDRESS 3131 GRAND AVE, SUITE B			
CITY and STATE LARAMIE, WY 82070		DATE 06-01-20 B	TO BE FILLED IN BY SUPPLIER			
TO BE FILLED IN BY PURCHASER			SUPPLIER'S DEA REGISTRATION No.			
LINE No.	No. of Packages	Size of Package	Name of Item	National Drug Code	Packages Shipped	Date Shipped
1	12	10ml	Etorphine HCl, 10mg/ml			
2	5	10ml	Carfentanil citrate, 3mg/ml			
3						
4						
5						
6						
7						
8						
9						
10						
D 2 NO. OF LINES COMPLETED		SIGNATURE OF PURCHASER OR HIS ATTORNEY OR AGENT E		BE SURE TO SIGN FORM		
Date Issued 06-23-94	DEA Registration No. BL9876543		Name and Address of Registrant			
Schedules 2,2N,3,3N,4,5			DOE, JOHN EDWARD DVM ABC VETERINARY CLINIC 1234 MAIN STREET ANYWHERE, USA			
Registered as a PRACTITIONER	No. of this Order Form 123456789		11223			
DEA Form -222 (Aug. 1990)		U.S. OFFICIAL ORDER FORMS - SCHEDULES I & II			45579700	
		DRUG ENFORCEMENT ADMINISTRATION			SUPPLIER'S Copy 1	

- a. Using a typewriter, computer printer, pen or indelible pencil, enter the supplier name, address, city, state, and zip in the appropriate fields **A**.
- b. Enter the date you are executing the form in the date field. **B**.
- c. Enter the number of packages, size, and concentration or quantity of the CS Schedule II material in the corresponding fields **C**. Only one item per line. You may have more than one package of the same item, though. When using triplicate forms, one form must be used exclusively for the purchase of any one of the following: carfentanil, etorphine hydrochloride, and diprenorphine. In these cases, no more than one item can be on the DEA 222 Form.
- d. Enter the number of lines used in the appropriate field. In this example, only two lines were used, so a "2" was entered in the area marked **D**.

- e. The CCSC must sign the form in the signature field .
- f. Copy Submission and Retention: Triplicate¹ vs. Single Copies:
- i. Triplicate Copies: All three copies must be completed as described, above. The CCSC shall retain Copy 3, pursuant to record retention requirements, and submit Copies 1 and 2 to the supplier via FEDEX overnight. At the time of submission, provide any other documentation required by the supplier (e.g. copy of license). The CCSC must retain Copy 3 for the respective license files and be able to present it for inspection by a DEA Officer if requested.
 - ii. Single Copy Forms: The original form must be completed as described, above. The CCSC must make a copy of the original single DEA 222 Form and submit the original to the supplier via FEDEX overnight. At the time of submission, provide any other documentation required by the supplier (e.g. copy of license). The copy of the original 222 Form may be maintained in paper or electronic form, pursuant to record retention requirements.
- g. The CCSC shall update the DEA 222 Excel File, to indicate, for the appropriate serial number, the date used and the CS Schedule II substances ordered. At this time, the reference highlight color should be changed to indicate the form has been used. On the CCSC DEA 222, highlight the box from Green to Orange.


OLAR DEA 222 Forms Tracking				
1	DEA 222 Form #	Date Forms Received	Date Used	Substances Listed
3	190684041	~11/2018	3/11/2019	Sufentanil Citrate
4	190684042	~11/2018	3/11/2019	VOIDED
5	190684043	~11/2018	3/25/2019	Fentanyl
6	190684044	~11/2018	7/1/2019	Morphine Sulfate, Fentanyl Citrate
7	190684045	~11/2018	7/24/2019	Morphine Sulfate
8	190684046	~11/2018	8/16/2019	Morphine
9	190684047	~11/2018		
10	192868510	~2/2019		
11	192868511	~2/2019		
12	192868512	~2/2019		
13	192868513	~2/2019		
14	192868514	~2/2019		
15	192868515	~2/2019		
16	192868516	~2/2019		
17	44579700	~2/2019	6/1/2020	

D. Receipt of DEA CS II Material

Upon receipt of the CSII Material:

- 1) The CCSC must record on their copy of the DEA 222 Form (whether it is Copy 3 or the copy of the single form), the number of containers (Packages Shipped) and the dates upon which those packages were received by (Date Shipped) Caltech.
- 2) The CCSC will generate a UDTD electronically using the CST System. In the “Notes” Section of the UDTD, enter the corresponding DEA 222 Form serial number. See Example:

¹ Triplicate forms will not be accepted after October 20, 2021.

		CALIFORNIA INSTITUTE OF TECHNOLOGY <small>CONTROLLED SUBSTANCES MANAGEMENT PROGRAM UNIFIED DISTRIBUTION, TRANSFER, AND DISPOSAL FORM</small>		FORM REVISION DATE 3/28/16	
DISTRIBUTION OF CS TO AUTHORIZED PERSON/RESEARCH GROUP					
AUTHORIZED PERSON:		SMITH, JANE (EXAMPLE ONLY)		RESEARCH GROUP: SMITH GROUP	
BUILDING:	Broad	ROOM:	B220A	IACUC/AUTHORIZATION #:	1427-17
CIT CONTROL NUMBER	9999	INVOICE NUMBER	DEA 222: 45579700 EXP: 02/2020		
GENERIC NAME	Etorphine	0033476255			
CS NAME	Etorphine	PO NUMBER			
CONTAINER	10 ml Vial	S390973			
CONCENTRATION UNITS	10 mg/mL	SUPPLIER			
SCHEDULE	CS-11				
DATE OF DELIVERY	01-JUN-20	ZOOPHARM			
DELIVERY:					
NAME:	Smith, John	SIGNATURE:		DATE:	06-JUN-20
RECEIVED BY:		SIGNATURE:		DATE:	
LAB A.P.:	Smith, Jane	SIGNATURE:		DATE:	06-JUN-20

3) When the UDTD forms have been printed and signed by the LCSC and the CCSC, attach a photocopy of the DEA 222 Form Copy 3/or original to the CCSC copy of the UDTD.

E. Records Retention – DEA 222 Forms

- 1) 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.
- 2) Any copies attached to the UDTD, must be retained along with the UDTD and are subject to the records retention requirement of the UDTD.

F. Loss of DEA 222 Forms

- If DEA 222 Forms become lost or destroyed, immediately report the incident to the IPOC along with the numbers of the DEA 222 forms that have been lost or destroyed.

G. DEA222 Forms for Reverse Distribution

- When CS Schedule II are released to a reverse distributor vendor, the vendor will issue a DEA222 form. These DEA222 Forms should be kept with the DEA Form 41 and maintained pursuant to the records retention requirements for the DEA Form 41. Upon completion of any DEA 222 forms, a copy of the DEA 222 should be send to the Registration Section of the local Los Angeles field office or emailed to DEA.Orderforms@usdoj.gov.