CONNECTICUT DEPARTMENT OF CONSUMER PROTECTION
DRUG CONTROL DIVISION

Manufacturer of Drugs, Medical Devices, and/or Cosmetics Mobile Inspection Form

The State of Connecticut Drug Control Division is utilizing all-inclusive mobile inspection forms that encompass multiple inspection types and business models. Inspection sections and/or inspection fields may intentionally remain blank when such sections and/or fields do not apply to the inspection type and/or business model for which the mobile inspection forms are being utilized. Please contact the Drug Control Agent who conducted your inspection if you feel an inspection section and/or inspection field was inadvertently left blank.

Manufacturer of Controlled Drugs

Controlled Drugs Handled by the Manufacturer	
Schedule II controlled drugs	
Schedule III controlled drugs	
Schedule IV controlled drugs	
Schedule V controlled drugs	

Controlled Drug Storage

Schedule II controlled drugs	Yes	No	Advised
PLEASE SELECT THE MANNER IN WHICH THE MANUFACTURER MUST STORE SCHEDULE II CONTROLLED DRUG STOCK			
The manufacturer's Schedule II stock totals less than 250 controlled drug units and must be stored in an approved safe. [Section 21a-262-4(a)]			
Is the manufacturer's Schedule II stock properly stored in an approved safe? [Section 21a-262-4(a)]			
The manufacturer's Schedule II stock totals 250 or more controlled drug units and must be stored in an approved vault. [Section 21a-262-4(a)]			
Is the manufacturer's Schedule II stock properly stored in an approved vault? [Section 21a-262-4(a)]			

Schedule III controlled drugs	Yes	No	Advised
PLEASE SELECT THE MANNER IN WHICH THE MANUFACTURER MUST STORE SCHEDULE III CONTROLLED DRUG STOCK			
Schedule III stock is stored in an approved vault [Section 21a-262-4(b)]			
Schedule III stock is stored in an approved safe equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			
Schedule III stock is stored in a separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			

Other			
Does the manufacturer store Schedule III stock in an approved manner? [Section 21a-262-4(b)]			

Schedule IV controlled drugs	Yes	No	Advised
PLEASE SELECT THE MANNER IN WHICH THE MANUFACTURER MUST STORE SCHEDULE IV CONTROLLED DRUG STOCK			
Schedule IV stock is stored in an approved vault [Section 21a-262-4(b)]			
Schedule IV stock is stored in an approved safe equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			
Schedule IV stock is stored in a separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			
Other			
Does the manufacturer store Schedule IV stock in an approved manner? [Section 21a-262-4(b)]			

Schedule V controlled drugs	Yes	No	Advised
PLEASE SELECT THE MANNER IN WHICH THE MANUFACTURER MUST STORE SCHEDULE V CONTROLLED DRUG STOCK			
Schedule V stock is stored in an approved vault [Section 21a-262-4(b)]			
Schedule V stock is stored in an approved safe equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			
Schedule V stock is stored in a separate secure locked caged area, room, or enclosure equipped with a separate effective electrical alarm system [Section 21a-262-4(b)]			
Other			
Does the manufacturer store Schedule V stock in an approved manner? [Section 21a-262-4(b)]			

	Controlled Drug Safe	Yes	No	Advised
1	Does the manufacturer's safe for the storage of controlled drug stock have a minimum of a "B" burglary rate? [Section 21a-262-1(f)(1)]			
2	Is the manufacturer's safe for the storage of controlled drug stock equipped with a re-locking device? [Section 21a-262-1(f)(2)]			

3	Does the manufacturer's safe for the storage of controlled drug stock weigh at least 750 pounds or is such safe rendered immobile by being securely anchored to a permanent structure of the building? [Section 21a-262-1(f)(3)]			
4	Does the manufacturer's safe for the storage of controlled drug stock have adequate interior space to store all controlled drugs required to be kept within the safe? [Section 21a-262-1(f)(4)]			
5	Does the pharmacy's new safe for the storage of controlled drug stock have any unused anchor holes?			
6	Did the pharmacy secure the unused anchor holes with carriage bolts, concrete anchoring adhesive, cement epoxy, or an equivalent?			
	Controlled Drug Vault	**Yes**	**No**	**Advised**
1	Are the walls, floor, and ceilings of the manufacturer's vault for the storage of controlled drug stock constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with 1/2 inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings? [Section 21a-262-1(g)(1)]			
2	Does the door of the manufacturer's vault for the storage of controlled drug stock contain a multiple-position combination lock or the equivalent? [Section 21a-262-1(g)(2)]			
3	Does the door of the manufacturer's vault for the storage of controlled drug stock contain a relocking device or the equivalent? [Section 21a-262-1(g)(2)]			

4	Does the door of the manufacturer's vault for the storage of controlled drug stock contain a steel plate with a thickness of at least one-half inch? [Section 21a-262-1(g)(2)]			
5	Is the manufacturer's vault for the storage of controlled drug stock equipped with a "day gate"?			
6	Is the manufacturer's vault's "day gate" self-closing and self-locking or the equivalent if operations require such vault to remain open for frequent access? [Section 21a-262-1(g)(3)]			
7	Are the walls, floor, and ceiling of the manufacturer's vault for the storage of controlled drug stock equipped with an alarm which, when unauthorized entry is attempted, transmits a signal directly to a central station protection company, or a local or state police agency which has a legal responsibility to respond, or a twenty-four-hour control station operated by the registrant? [Section 21a-262-1(g)(4)]			
8	Is the door of the manufacturer's vault for the storage of controlled drug stock equipped with a contact switch? [Section 21a-262-1(g)(5)]			
9	Is the electrical system of the manufacturer's vault for the storage of controlled drug stock certified as being an Underwriters Laboratories, Inc., approved system and installation? [Section 21a-262-1(g)(7)]			
10	**PLEASE SELECT EACH FEATURE THAT THE MANUFACTURER'S VAULT HAS FOR THE STORAGE OF CONTROLLED DRUG STOCK**			
	Complete electrical lacing of the walls, floor and ceiling [Section 21a-262-1(g)(6)(a)]			
	Sensitive ultrasonic equipment within the vault [Section 21a-262-1(g)(6)(b)]			
	A sensitive sound accumulator system [Section 21a-262-1(g)(6)(c)]			
	Such other device designed to detect illegal entry as may be approved by the Commissioner of Consumer Protection [Section 21a-262-1(g)(6)(d)]			

10 (cont'd)	Does the manufacturer's vault for the storage of controlled drug stock have at least one of the four features listed above? [Section 21a-262-1(g)(6)]			
	Controlled Drug Security	**Yes**	**No**	**Advised**
1	Has the manufacturer provided safeguards which can be regarded in toto as an adequate substitute for some element of protection required of such manufacturer? (e.g. supervised watchman service, full electrical protection of the building, electric alarms, etc.) [Section 21a-262-2(a)]			
2	Does the manufacturer maintain all stocks of controlled drugs in all schedules in a secure area or location accessible only to specifically authorized personnel? [Section 21a-262-2(b)]			
3	Does the manufacturer store all controlled drugs in such a manner as to prevent theft or diversion of these preparations? [Section 21a-262-2(b)]			
4	Does the manufacturer maintain all equipment used for storage of controlled drugs such as approved vault(s), approved safe(s), caged areas, cabinets, enclosures, etc. securely locked except for the actual time required to remove or replace needed items? [Section 21a-262-2(c)]			
5	Does the manufacturer keep locks in good working order with keys removed therefrom? [Section 21a-262-2(c)]			
6	Does the manufacturer ensure that keys to locks are not left in a location accessible to other than specifically authorized personnel? [Section 21a-262-2(c)]			
7	Does the manufacturer maintain any stock of controlled drugs in excess of the quantity actually required for normal, efficient operation? [Section 21a-262-2(g)]			

8	Does the manufacturer store all controlled drugs in the process of manufacture, distribution, transfer, or analysis in such a manner as to prevent diversion? [Section 21a-262-4(c)]			
9	Does the manufacturer return all controlled drugs in the process of manufacture, distribution, transfer, or analysis to the required security location immediately after completion of the procedure or at the end of the scheduled business day? [Section 21a-262-4(c)]			
10	Does the manufacturer limit accessibility to all controlled drugs in the process of manufacture, distribution, transfer, or analysis to only the minimum number of specifically authorized personnel essential for efficient operation? [Section 21a-262-4(c)]			

Schedule II Orders

PLEASE SELECT THE MANNER IN WHICH THE MANUFACTURER PROCURES SCHEDULE II CONTROLLED DRUG STOCK

DEA 222 Forms [CFR Part 1305 Subpart B-DEA Form 222]	
Controlled Substance Ordering System (CSOS) [CFR Part 1305 Subpart C-Electronic Orders and CFR Part 1311 Subpart B-Obtaining and Using Digital Certificates for Electronic Orders]	
A combination of DEA 222 Forms and CSOS	

	DEA 222 Orders	Yes	No	Advised
1	Who is documented as the manufacturer's DEA registrant on the manufacturer's DEA registration certificate?			
2	Did the DEA registrant grant power of attorney to sign DEA 222 order forms? [CFR 1305.05(a)]			
3	Are the manufacturer's power(s) of attorney available for inspection? [CFR 1305.05(a)]			
4	Did any individual sign DEA 222 order forms who was not granted power of attorney by the manufacturer's DEA registrant to sign such forms? [CFR 1305.05(a)]			

5	Does the manufacturer maintain unexecuted DEA 222 order forms in an organized manner?			
6	Does the manufacturer keep unexecuted DEA 222 order forms securely in a limited access area?			
7	Does the manufacturer have any "pre-signed" unexecuted DEA 222 order forms?			
8	Are the manufacturer's executed DEA 222 order forms readily available for inspection? [Section 21a-261(a)]			
9	Does the manufacturer maintain executed DEA 222 order forms separately apart from other drug records? [Section 21a-254(f)]			
10	Does the manufacturer maintain executed DEA 222 order forms in an organized manner?			
11	Are the manufacturer's executed DEA 222 order forms properly executed? [CFR 1305.12]			

	CSOS Orders	Yes	No	Advised
1	Who is documented as the manufacturer's DEA registrant on the manufacturer's DEA registration certificate?			
2	Did the DEA registrant grant power of attorney to sign CSOS orders? [CFR 1311.45]			

3	Does the DEA registrant maintain a record that lists each person granted power of attorney to sign CSOS orders? [CFR 1311.45(b)]			
4	Did any individual sign CSOS orders to whom the DEA registrant did not grant power of attorney to sign such orders? [CFR 1311.45]			
5	Does the manufacturer properly secure CSOS private key(s)? [CFR 1311.30]			
6	Do the manufacturer's CSOS certificate holders maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate? [CFR 1311.60(c)]			
7	Does the manufacturer maintain CSOS records on a central server? [CFR 1305.27(c)]			
8	Are the manufacturer's CSOS records readily retrievable at the registered location? [CFR 1305.27(c)]			
9	Are the manufacturer's electronically-maintained CSOS records readily retrievable from all other records? [CFR 1311.60(a)]			
10	Are the manufacturer's electronically-maintained CSOS records easily readable or easily rendered into a format that a person can read? [CFR 1311.60(b)]			

11	Does the manufacturer retain for each CSOS order filled the original signed order and all linked records for that order for three years from the date of the transaction recorded? [CFR 1305.27(a), CFR 1311.60, and Section 21a-254(f)]			
12	Does the manufacturer retain all copies of each unaccepted or defective CSOS order and each linked statement for three years from the date of the transaction recorded? [CFR 1305.27(a), CFR 1311.60(a), and Section 21a-254(f)]			
13	Does the manufacturer retain an electronic copy of all voided CSOS orders for three years from the date of the transaction recorded? [CFR 1305.28(b), CFR 1311.60(a), and Section 21a-254(f)]			
	Where does the manufacturer store CSOS orders for a period of three years from the date of the transaction recorded?			
	Cloud			
	Electronic File			
	Flash Drive			
	Other			
	Paper File			
14	Does the manufacturer complete and verify CSOS orders in CSOS upon receipt from the supplier?			
	Receipt Records	**Yes**	**No**	**Advised**
1	Does the manufacturer maintain receipt records of controlled drugs that bear the date on which controlled drugs were received? [Section 21a-254(f)]			
2	Does the manufacturer maintain receipt records of controlled drugs that bear the name of person from whom controlled drugs were received? [Section 21a-254(f)]			

3	Does the manufacturer maintain receipt records of controlled drugs that bear the address of person from whom controlled drugs were received? [Section 21a-254(f)]			
4	Does the manufacturer maintain receipt records of controlled drugs that bear the kind of controlled drugs received? [Section 21a-254(f)]			
5	Does the manufacturer maintain receipt records of controlled drugs that bear the quantity of controlled drugs received? [Section 21a-254(f)]			
6	Does the manufacturer keep receipt records of controlled drugs on the manufacturer's premises? [Section 21a-254(h)]			
7	Does the manufacturer maintain receipt records of controlled drugs current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
8	Does the manufacturer maintain receipt records of controlled drugs separately apart from other drug records? [Section 21a-254(f)]			
9	Are the manufacturer's receipt records of controlled drugs void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
10	Does the manufacturer keep records of all controlled drugs received by them separately apart from other drug records for a period of three years from the date of the transaction recorded? [Section 21a-254(d)]			

	Disposition Records	Yes	No	Advised
1	Does the manufacturer maintain disposition records of controlled drugs that bear the date on which controlled drugs were disposed? [Section 21a-254(f)]			
2	Does the manufacturer maintain disposition records of controlled drugs that bear the kind of controlled drugs disposed? [Section 21a-254(f)]			
3	Does the manufacturer maintain disposition records of controlled drugs that bear the quantity of controlled drugs disposed? [Section 21a-254(f)]			
4	Does the manufacturer maintain disposition records of controlled drugs that bear the name of the person to whom or for whose use controlled drugs were used? [Section 21a-254(f)]			
5	Does the manufacturer keep disposition records of controlled drugs on the manufacturer's premises? [Section 21a-254(h)]			
6	Does the manufacturer maintain disposition records of controlled drugs current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
7	Does the manufacturer maintain disposition records of controlled drugs separately apart from other drug records? [Section 21a-254(f)]			

8	Are the manufacturer's disposition records of controlled drugs void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
9	Does the manufacturer keep records of all controlled drugs disposed of by them separately apart from other drug records for a period of three years from the date of the transaction recorded? Section 21a-254(d)]			

Inventory Records				
	General Information	Yes	No	Advised
1	Does the manufacturer maintain inventory records of controlled drugs that bear the DATE on which the initial or annual inventory was CONDUCTED? [CFR 1304.11(a)]			
2	Does the manufacturer maintain inventory records of controlled drugs that bear the TIME of day the initial or annual inventory was COMPLETED (opening of business or close of business)? [CFR 1304.11(a)]			
24	Does the manufacturer maintain inventory records of controlled drugs that bear the COMPLETE LISTING of all controlled drugs ON HAND? [CFR 1304.11(a) and Section 21a-254(h)]			
25	Did the manufacturer prepare an inventory of all controlled drugs on hand on the date the manufacturer first engaged in the manufacture of controlled drugs? [CFR 1304.11(b)]			
26	Does the manufacturer prepare annually within four days of the first day of May of the calendar year a complete and accurate record of all controlled drugs on hand on the date the inventory is taken? [Section 21a-254(h)]			

27	Does the manufacturer maintain the initial and annually prepared complete and accurate records of all controlled drugs on hand in written, typewritten, or printed form at the manufacturer's registered location? [CFR 1304.11(a) and Section 21a-254(h)]			
28	Does the manufacturer maintain the initial and annually prepared complete and accurate records of all controlled drugs on hand current and separate from other business records in such form as to be readily available for inspection at reasonable times? [Section 21a-254(h) and Section 21a-261]			
29	Are the manufacturer's initial and annually prepared complete and accurate records of all controlled drugs on hand void of the use of a foreign language, codes, or symbols to designate controlled drugs or persons in the keeping of such records? [Section 21a-254(h)]			
30	Does the manufacturer keep the initial and annually prepared complete and accurate records of all controlled drugs on hand on file for three years? [Section 21a-254(h)]			
	BULK FORM Controlled Drugs	**Yes**	**No**	**Advised**
3	Does or did the manufacturer have any controlled drugs in BULK FORM to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled drugs in finished form on the inventory date?			
4	Does the manufacturer maintain inventory records of controlled drugs that bear the NAME of the CONTROLLED DRUG inventoried? [CFR 1304.11(e)(1)(i)(A)]			
5	Does the manufacturer maintain inventory records of controlled drugs that bear the TOTAL QUANTITY of the CONTROLLED DRUG inventoried to the nearest metric unit weight consistent with unit size? [CFR 1304.11(e)(1)(i)(B)]			

	IN THE PROCESS OF MANUFACTURE Controlled Drugs	Yes	No	Advised
6	Does or did the manufacturer have any controlled drugs IN THE PROCESS OF MANUFACTURE on the inventory date?			
7	Does the manufacturer maintain inventory records of controlled drugs that bear the NAME of the CONTROLLED DRUG inventoried? [CFR 1304.11(e)(1)(ii)(A)]			
8	Does the manufacturer maintain inventory records of controlled drugs that bear the QUANTITY of CONTROLLED DRUG inventoried in each batch and/or stage of manufacture? [CFR 1304.11(e)(1)(ii)(B)]			
9	Is the quantity of controlled drug inventoried in each batch and/or stage of manufacture identified by the BATCH NUMBER or APPROPRIATE IDENTIFYING NUMBER? [CFR 1304.11(e)(1)(ii)(B)]			
10	Does the manufacturer maintain inventory records of controlled drugs that bear the PHYSICAL FORM which the inventoried controlled drug is to take UPON COMPLETION OF the MANUFACTURING PROCESS (e.g., granulations, tablets, capsules, or solutions)? [CFR 1304.11(e)(1)(ii)(C)]			
11	Is the physical form which the inventoried controlled drug is to take upon completion of the manufacturing process identified by the BATCH NUMBER or OTHER APPROPRIATE IDENTIFYING NUMBER? [CFR 1304.11(e)(1)(ii)(C)]			
12	Does the manufacturer maintain inventory records of controlled drugs that bear the FINISHED FORM of the inventoried CONTROLLED DRUG (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter), if possible? [CFR 1304.11(e)(1)(ii)(C)]			

13	Does the manufacturer maintain inventory records of controlled drugs that bear the NUMBER OR VOLUME of the FINISHED FORM of the inventoried controlled drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter), if possible? [CFR 1304.11(e)(1)(ii)(C)]			
	FINISHED FORM Controlled Drugs	**Yes**	**No**	**Advised**
14	Does or did the manufacturer have any controlled drugs IN FINISHED FORM on the inventory date?			
15	Does the manufacturer maintain inventory records of controlled drugs that bear the NAME of each controlled drug inventoried? [CFR 1304.11(e)(1)(iii)(A)]			
16	Does the manufacturer maintain inventory records of controlled drugs that bear the FINISHED FORM of each controlled drug (e.g. 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) inventoried? [CFR 1304.11(e)(1)(iii)(B)]			
17	Does the manufacturer maintain inventory records of controlled drugs that bear the NUMBER OF UNITS OR VOLUME of each finished form of each inventoried controlled drug in each commercial container (e.g. 100-tablet bottle or 3-milliliter vial)? [CFR 1304.11(e)(1)(iii)(C)]			
18	Does the manufacturer maintain inventory records of controlled drugs that bear the NUMBER OF commercial CONTAINERS of each finished form (e.g. four 100-tablet bottles or six 3-milliliter vials) of each inventoried controlled drug? [CFR 1304.11(e)(1)(iii)(D)]			
	DAMAGED, DEFECTIVE, IMPURE, AWAITING DISPOSAL, QUALITY CONTROL, COMPOUNDING Controlled Drugs	**Yes**	**No**	**Advised**
19	Does or did the manufacturer have any controlled drugs that are DAMAGED, DEFECTIVE, IMPURE, awaiting disposal, held for quality control purposes, or maintained for extemporaneous compounding on the inventory date?			

20	Does the manufacturer maintain inventory records of controlled drugs that bear the NAME of the CONTROLLED DRUG inventoried? [CFR 1304.11(e)(1)(iv)(A)]			
21	Does the manufacturer maintain inventory records of controlled drugs that bear the TOTAL QUANTITY of the CONTROLLED DRUG inventoried to the nearest metric unit weight or the total number of units of finished form? [CFR 1304.11(e)(1)(iv)(B)]			
22	Does the manufacturer maintain inventory records of controlled drugs that bear the REASON why the registrant is MAINTAINING the inventoried controlled drugs? [CFR 1304.11(e)(1)(iv)(C)]			
23	Does the manufacturer maintain inventory records of controlled drugs that bear WHETHER the inventoried controlled drugs are CAPABLE OF USE in the manufacture of any controlled drug in finished form? [CFR 1304.11(e)(1)(iv)(C)]			

	Additional Comments	Yes	No	
1	Does the inspecting agent have any additional comments with respect to this manufacturer inspection?			