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.

Non-FDA Registered Manufacturer of Drugs, Medical Devices, and/or Cosmetics Compliance, Opening, and Relocation Inspection Form

Type(s) of Business Conducted in Connecticut	
Cosmetics	
Drugs - Non-Legend	
Drugs - Legend Non-Controlled	
Drugs - Legend Controlled	
Durable Medical Equipment	
Medical Devices	
Medical Gases	
Other	

	Personnel	Yes	No	Advised
1	Are personnel appropriately trained and qualified to perform their assigned duties?			
2	Are personnel capable of performing their assigned duties?			
3	Do personnel have documentation of initial and ongoing training for their assigned duties?			
4	Is the documentation of initial and ongoing training for personnel maintained in a readily retrievable manner?			

	Ingredients	Yes	No	Advised
5	Are manufacturing ingredients of the appropriate identity, purity, and quality?			
6	Are manufacturing ingredients purchased from reliable sources?			
7	Are manufacturing ingredients properly stored in accordance with manufacturer specifications and/or USP standards?			

	Environment	Yes	No	Advised
8	Is the manufacturing environment suitable for its intended purpose?			
9	Is access to the immediate vicinity in which manufacturing operations are performed limited to authorized personnel only?			
10	Are manufacturing activities performed in an appropriately cleaned and sanitized dedicated area?			
11	Does the manufacturing area have a dedicated and labeled quarantine area for damaged, recalled, and adulterated products?			
12	Is the manufacturing area equipped with or has ready access to a sink?			
13	Is the manufacturing area monitored for temperature and humidity?			

14	Does the manufacturing area have adequate ventilation?			
15	Is the manufacturing area is clean and organized?			
16	Is the manufacturing area free of vermin, pests, and insects?			
	Security	**Yes**	**No**	**Advised**
17	Is the manufacturing facility equipped with an alarm system that is capable of detecting unauthorized access outside of normal business hours?			
18	Is the outside perimeter of manufacturing facility is well lit?			
19	Do bulk manufacturer containers bear appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels (OSHA.gov) when applicable?			
20	Are Material Safety Data Sheets (MSDS) available for all chemicals used in the manufacturing process when applicable?			
21	Are finished products labeled with the manufacturer's information along with batch numbers and expiration dates?			
	Documentation	**Yes**	**No**	**Advised**
22	Are all aspects of manufacturing are appropriately documented including, but not limited to, freezer, refrigerator, and room temperatures?			

23	Are master formulation records created prior to manufacturing a product for the first time?			
24	Are manufacturing records created each time a product is manufactured?			
25	Are master formulation records followed each time a product is manufactured?			
26	Is documentation maintained in an organized manner for the period of time required under law?			
	Quality Assurance	**Yes**	**No**	**Advised**
27	Is only one product manufactured at any given time in a dedicated workspace?			
28	Are manufacturing conditions adequate for preventing errors?			
29	Do manufacturers review each step of the manufacturing process to ensure accuracy, completeness, and expected yield of the finished product?			
30	Do manufacturers observe the finished product to ensure it appears as expected and if necessary, investigate any and all discrepancies?			
31	Is manufacturing equipment clean, properly maintained, and used appropriately?			

	Equipment	Yes	No	Advised
32	Is manufacturing equipment appropriate for its intended purpose?			
33	Is manufacturing equipment inspected for cleanliness and correct functioning?			
34	Is manufacturing equipment is dedicated solely to manufacturing activities?			

	Policies and Procedures	Yes	No	Advised
35	Are procedures in place to prevent cross contamination?			
36	Are procedures in place to assure manufacturing processes are reproducible?			
37	Are procedures in place to assure manufacturing processes are carried out as intended/specified?			
38	Are procedures in place for preventing, detecting, and handling errors?			
39	Are procedures in place for tracking products in the event of a recall?			
40	Are procedures in place that allow the manufacturer to systematically trace, evaluate, and replicate each step of the manufacturing process?			

41	Are policies and procedures readily available for review in either a written or electronic format?			
42	Are procedures in place that allow the manufacturer to systematically trace, evaluate, and replicate each step of the manufacturing process?			
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	Additional Comments	**Yes**	**No**	
1	Does the inspecting agent have any additional comments with respect to this manufacturer inspection?			