Kansas	STATE BOARD OF PHARMACY 800 SW Jackson, Suite 1414 Topeka, Kansas 66612-1244 www.pharmacy.ks.gov (785)296-4056	INSPECTION: Distributor Form I-05

Clear Answers

INSPECTION INFORMATION

Distributor Name:_____ Registration Number:_____

Inspector Name: _____ Date: _____

Facility Type:

C-Compliant N/I-Needs Improvement N/C-Not Compliant
U-Unassessed N/A-Not Applicable

☐ Human Prescription Drugs ☐ Animal Prescription Drugs

☐ Oxygen/Medical Gases ☐ Medical Devices ☐ Nonprescription Drugs ☐ Dialysates—K.S.A. 65-1660 ☐ Other

GENERAL INFORMATION

Person(s) on duty: _____

C N/I N/C U N/A Registration(s) displayed—K.S.A. 65-1645(e) & K.A.R. 68-14-7(f)(5)

C N/I N/C U N/A DEA number: _____—21 C.F.R. 1301.11

PRACTICE SETTING

Does the facility distribute oxygen: ☐ Yes ☐ No

If distributed, transfilled on site by facility: ☐ Yes ☐ No

If yes, FDA registration number: _____ Date of last FDA inspection: _____

If no, who transfills oxygen: _____

FACILITIES

C N/I N/C U N/A Suitable size and construction to facilitate cleaning, maintenance, & proper operation —K.A.R. 68-14-7(a)(1)

C N/I N/C U N/A Adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, & security —K.S.A. 65-656(m) & K.A.R. 68-14-7(a)(2)

C N/I N/C U N/A Quarantine area—K.A.R. 68-14-7(a)(3)

C N/I N/C U N/A Maintained in a clean and orderly condition—K.A.R. 68-14-7(a)(4)

C N/I N/C U N/A Free from infestation by insects, rodents, birds, or vermin of any kind—K.A.R. 68-14-7(a)(5)

C N/I N/C U N/A Drugs and devices stored per manufacturer—K.A.R. 68-14-7(c)

C N/I N/C U N/A Documentation of appropriate temperature—K.A.R. 68-14-7(c)(2)

Room temperature: _____

Refrigerator temperature: _____

Freezer temperature: _____

C N/I N/C U N/A Establish, maintain and adhere to policy and procedures—K.A.R. 68-14-7(g)

C N/I N/C U N/A Procedures for distribution of oldest approved stock first—K.A.R. 68-14-7(g)(1)

C N/I N/C U N/A Procedure for handling recalls and withdrawing drugs and devices—K.A.R. 68-14-7(g)(2)

C N/I N/C U N/A Procedure to prepare for, protect against and handle any crisis that affects security or operation of

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facility—K.A.R. 68-14-7(g)(3)

○C ○N/I ○N/C ○U ○N/A Procedure for outdated, mislabeled, or adulterated drugs and devices to be removed from stock —K.S.A. 65-1634, K.S.A. 65-657(a), K.A.R. 68-14-7(e) & K.A.R. 68-14-7(g)(4)

○C ○N/I ○N/C ○U ○N/A Drugs and devices distributed to registered sources —21 C.F.R. 1301.74(a), K.S.A. 65-1643(c) & K.A.R. 68-14-7(g)(5)

SECURITY

○C ○N/I ○N/C ○U ○N/A Secure from unauthorized entry—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7(b)(1)

○C ○N/I ○N/C ○U ○N/A Alarm and security systems—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7(b)(2) & (3)

○C ○N/I ○N/C ○U ○N/A Perimeter of premises well lighted—K.A.R. 68-17-7a(b)(1)

○C ○N/I ○N/C ○U ○N/A Controlled drugs locked—21 C.F.R. 1301.71 thru 1301.76 & K.A.R. 68-14-7(b)(4), K.A.R. 68-20-15a

○C ○N/I ○N/C ○U ○N/A Verification that persons or entities that transport on their behalf utilize processes to ensure product security—21 C.F.R. 1301.74 & K.A.R. 68-14-7(b)(5)

RECORDS

○C ○N/I ○N/C ○U ○N/A Documentation of education, training & experience—K.A.R. 68-14-5

○C ○N/I ○N/C ○U ○N/A Maintain list of responsible persons to include duties and qualifications —K.A.R. 68-14-7(h)

○C ○N/I ○N/C ○U ○N/A Documentation of examination of materials—K.A.R. 68-14-7(d)

○C ○N/I ○N/C ○U ○N/A Oxygen prescriptions contain all required elements and are renewed annually—K.S.A. 65-1637

○C ○N/I ○N/C ○U ○N/A Records of ALL transactions in the receipt and distribution of prescription-only drugs and devices —K.A.R. 68-14-7(f)

○C ○N/I ○N/C ○U ○N/A Duration of record keeping—K.A.R. 68-20-16(a) & K.A.R. 68-14-7(f)(3)

○C ○N/I ○N/C ○U ○N/A Central record keeping—K.A.R. 68-14-7(f)(4) & 21 C.F.R. 1304.04(b)(3)

Location: _____

○C ○N/I ○N/C ○U ○N/A Records readily retrievable—K.A.R. 68-14-7(f)(3) & (4)

REVIEW OF INVENTORY AND INVOICE RECORDS

○C ○N/I ○N/C ○U ○N/A Drugs and devices distributed to registered sources —21 C.F.R. 1301.74, K.S.A. 65-1643(c), K.A.R. 68-14-7(f)(2) & K.A.R. 68-14-7(g)(5)

○C ○N/I ○N/C ○U ○N/A Inventories and records of all transactions—K.A.R. 68-14-7(f)

○C ○N/I ○N/C ○U ○N/A Annual inventory of controlled substances—K.A.R. 68-20-16

Date: _____

○C ○N/I ○N/C ○U ○N/A C-II inventory filed separately—K.A.R. 68-20-16

○C ○N/I ○N/C ○U ○N/A C-II invoices filed separately—K.A.R. 68-20-16

○C ○N/I ○N/C ○U ○N/A CIII-V invoices filed separately or readily retrievable—K.A.R. 68-20-16

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C N/I N/C U N/A DEA 222 forms completed—21 C.F.R. 1305.12 & 1305.13

C N/I N/C U N/A DEA 222 forms for C-II transfers—K.A.R. 68-20-17

C N/I N/C U N/A Power of attorney—21 C.F.R. 1305.05

VETERINARY WHOLESALE DISTRIBUTORS—K.A.R. 68-14-8

C N/I N/C U N/A Original prescriptions and written confirmations maintained on file for 5 years

C N/I N/C U N/A Delivery personnel carry copies of prescriptions and written confirmations

C N/I N/C U N/A Original prescriptions received within 72 hours for all written confirmations

C N/I N/C U N/A Written confirmations taken directly from DVM and include: name of DVM, date and time verbal order received, and name of person receiving the confirmation

C N/I N/C U N/A Prescriptions and written confirmations meet all requirements for a veterinary prescription —K.A.R. 70-7-1(l)&(m)

COMMENTS

Self-Inspection