

NAME and ADDRESS OF FACILITY

Reviewed by _____ Pharmacy Inspector

Nebraska Revised Statutes 71-8901 to Section 79-8929 are known as the Veterinary Drug Distribution Licensing Act.

71-8914 requires written policies and procedures. A veterinary drug distributor shall establish, maintain, and adhere to written policies and procedures for the receipt, storage, security, inventory, and distribution of veterinary legend drugs, including policies for identifying, recording, and reporting destruction, losses, or thefts of veterinary legend drugs and for correcting all errors and inaccuracies in inventories. The policies shall contain a provision for annual review at which time the policies shall be updated as necessary. A record documenting the review shall be kept with the policies and procedures and shall indicate the date of the review and the signature of the designated representative of the veterinary drug distributor. The determination of the passage or failure of these requirements is based on 71-8914, the standards under 181-005 below and documentation provided by the applicant.

71-8915 enables the Department to issue a provisional license to any applicant who meets the following conditions:

1. The applicant has not been found to have committed any of the acts or offenses described in Section 71-8917;
2. The applicant has established written policies and procedures as required by section 71-8914; and
3. The applicant has paid a fee of five hundred dollars. The determination of the failure or passage of these requirements is based on 71-8915, the standards under 181-005 below and documentation provided by the applicant.

71-8923 Establishes Limitations on Veterinary Drug Distributors. A veterinary drug distributor shall not:

1. Operate from a place of residence. Pass _____ Fail _____
2. Possess, sell, purchase, trade or otherwise furnish controlled substances.
Pass _____ Fail _____
3. Possesses, sell, purchase, trade or otherwise furnish human legend drugs.
Pass _____ Fail _____

The determination of the passage or failure to meet these limitations is based upon 71-8923 and documentation submitted by the applicant.

(Note: Failure of any limitation of 71-8923 shall result in denial of the issuance of the Veterinary Drug Distributor License.

The following draft regulations shall be used by the State Pharmacy Inspectors to screen/review the documents, policies and procedures and other requested information submitted by the applicant for the Veterinary Drug Distribution License, until such time as the regulations are finalized. Based upon the Pharmacy Inspectors review and their recommendation the Department may issue the provisional license.

181-005 STANDARDS FOR ENGAGING IN VETERINARY DRUG DISTRIBUTION

181-005.01 Personnel: A veterinary drug distributor must employ staff to operate the veterinary drug distribution facility pursuant to 172 NAC 181. To this end, the veterinary drug distributor must designate a representative to be in charge of veterinary drug distribution and the storage and handling of all drugs. Such designated representative must:

1. Have knowledge of federal and state statutes applicable to veterinary drug distribution; Pass _____ Fail _____
Not Applicable/Reason _____
2. Have had no convictions under any federal, state, or local laws relating to veterinary drug distribution or human legend drug distribution; Pass ____ Fail ____
Not applicable _____
3. Have a minimum of two years of verifiable full-time managerial or supervisory experience in a veterinary drug distributor or human legend drug distributor licensed in this state or another state, where the designated representative's responsibilities included but were not limited to recordkeeping, storage, and shipment of veterinary legend drugs or human legend drugs; Pass ____ Fail _____
Not applicable _____
4. Be actively involved in and aware of the actual daily operations of the veterinary drug distributor:
 - a. Employed full-time in a managerial position by the veterinary drug distributor; Pass _____ Fail _____
Not applicable _____
 - b. Physically present at the veterinary drug distributor during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence; Pass ____ Fail ____ Not applicable _____ and _____
 - c. Aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the veterinary drug distributor. Pass ____ Fail ____
N/A and reason _____
N/A _____

181-005.02 Facility: All facilities at which veterinary legend drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from must:

1. Be of suitable construction to ensure that all veterinary legend drugs in the facilities are maintained in accordance with the product labeling of such veterinary legend drugs, or in compliance with official compendium standards such as the United States Pharmacopeia–USP/NF; Pass ____ Fail ____
Not applicable _____
2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper veterinary drug distribution operations;
3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions; Pass ____ Fail ____
Not applicable _____
4. Have a quarantine area for storage of veterinary legend drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution or veterinary drug distribution, or that are in immediate or sealed secondary containers that have been opened;
Pass ____ Fail ____
Not applicable _____
5. Be maintained in a clean and orderly condition; Pass _____ Fail _____
Not applicable _____
6. Be free from infestation of any kind; Pass _____ Fail _____ Not applicable _____
7. Be a commercial location and not a personal dwelling or residence;
Pass ____ Fail ____

Not applicable _____

8. Provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information; Pass _____ Fail _____
Not applicable _____

; and

9. Provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of veterinary legend drugs. Pass _____ Fail _____
Not applicable _____

Inspector Overall Review of Facility Standard Documentation: _____ Pass
_____ Fail _____ N/A & Reason N/A

181-005.03 Policies and Procedures: Veterinary drug distributors must establish, maintain, and adhere to written policies and procedures. The policies and procedures must contain a provision for annual review and update, and documentation of the review must be maintained with the policies and procedures and include date and signature of the designated representative. The written policies and procedures must include the following:

1. A procedure to be followed for handling recalls and withdrawals of veterinary legend drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:
 - a. Any action initiated at the request of FDA or any other federal, state, or local law enforcement or other government agency, including the Department; or
 - b. Any volunteer action by the manufacturer to remove defective or potentially defective veterinary legend drugs from the market. Pass _____ Fail _____
Not applicable _____
2. A procedure for guarding against losses and/or employee theft. Pass _____ Fail _____
3. A procedure for identifying, recording, and reporting destruction, losses or thefts of veterinary legend drugs, and for correcting all errors and inaccuracies in inventories. Pass _____ Fail _____
4. A procedure for reporting criminal or suspected criminal activities involving the inventory of veterinary legend drug(s) to the Department within five business days. Pass _____ Fail _____
5. A procedure to ensure that veterinary drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of a strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency. Pass _____ Fail _____
6. A procedure that provides for inspection of all incoming and outgoing veterinary legend drug shipments. Pass _____ Fail _____
7. A procedure to ensure that any outdated veterinary legend drugs must be segregated from other veterinary legend drugs and are then either returned to the manufacturer or a reverse distributor or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure must provide for written documentation of the disposition of outdated veterinary legend drugs. This documentation must be maintained for two years after disposition of the outdated veterinary legend drugs. Pass _____ Fail _____
8. A procedure for the destruction of outdated veterinary legend drugs in accordance with federal and state laws, including all necessary documentation, maintained for a minimum of three years, and the appropriate witnessing of the destruction of outdated veterinary legend drugs in accordance with all applicable federal and state requirements. Pass _____ Fail _____
9. A procedure for the disposing and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of three

years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements. Pass _____ Fail _____

10. A procedure for identifying, investigating and reporting significant veterinary legend drug inventory discrepancies involving counterfeit, suspect of being counterfeit, contraband, or suspect of being contraband, in the inventory and reporting of such discrepancies within five business days to the Department and/or appropriate federal or state agency upon discovery of such discrepancies. Pass _____ Fail _____

Inspector Overall Review of Policy and Procedure Standard: Pass _____ Fail _____

181-005.04 Records: A veterinary drug distributor must have records to document all drug purchases and sales.

181-005.04A Veterinary drug distributors must establish and maintain inventories and records of all transactions regarding the receipt and veterinary drug distribution or other disposition of veterinary legend drugs. These records must include dates of receipt and veterinary drug distribution or other disposition of the veterinary legend drugs; Pass _____ Fail _____ and

181-005.04B Such records must include the inventories and records must be made available for inspection and photocopying by any authorized official of any state or federal governmental agency for a period of three years following their creation date. Pass _____ Fail _____

181-005.04C Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable must be made available for inspection within 48 hours of a request by an authorized official of any state or federal governmental agency charged with enforcement of these rules. Pass _____ Fail _____

181-005.04D Veterinary drug distributors and manufacturers must maintain an ongoing list of persons with whom they do business to sell or purchase veterinary legend drugs. Pass _____ Fail _____

181-005.04E All facilities must establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs or counterfeiting and contraband or suspected counterfeiting and contraband activities to the Department and FDA. Pass _____ Fail _____

181-005.04F Veterinary drug distributors must maintain a system for the mandatory reporting of significant shortages or losses of veterinary legend drugs where it is known or suspected that diversion is occurring to the Department and FDA, and, where applicable, to DEA. Pass _____ Fail _____

181-005.04G Records must be maintained by the veterinary drug distributor to document all purchases, sales, destruction, transfer, loss, and return of veterinary legend drugs. Pass _____ Fail _____

181-005.04H Records may be kept manually or by electronic or automated means. When an automated recordkeeping system is used, there must be a complete back-up system every seven days that is verifiable to prevent loss of records. Pass _____ Fail _____

Inspector Overall Review of Records Standard: Pass _____ Fail _____

INSPECTOR OVERALL REVIEW OF THE APPLICATION: Pass _____ Fail _____
More information is required as follows: