



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES**



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**MODIFIED CLASS II INSTITUTIONAL PERMIT  
ANIMAL CONTROL SHELTER**

File # \_\_\_\_\_  
Insp # \_\_\_\_\_

ROUTINE  CHANGE LOC  NEW  CURRENTLY NOT OPERATING  CHANGE OWNER

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ANIMAL SHELTER			PERMIT NUMBER			DATE OF INSPECTION		
DOING BUSINESS AS			DEA NUMBER			ON-SITE MANAGER OF SHELTER		
STREET ADDRESS			TELEPHONE #		EXT.			
CITY		COUNTY		STATE/ZIP				
<b>PRESCRIPTION DEPARTMENT HOURS</b>								
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	
Open								
Close								
SATISFACTORY				YES NO				
1	Current Modified Class II Institutional Pharmacy permit [465.019(2) (c), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>			
2	Board of Pharmacy Office notified of on-site manager change within 10 days. [64B16-29.002(6), F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
3	Current DEA registration for II N and III N Controlled Substances. [21 CFR1301.11]			<input type="checkbox"/>	<input type="checkbox"/>			
4	Controlled sub. inventory taken on biennial basis and available for inspection [893.07 (1)(a) , F.S.]			<input type="checkbox"/>	<input type="checkbox"/>			
5	Controlled substance records readily retrievable. [893.07, F.S.]			<input type="checkbox"/>	<input type="checkbox"/>			
6	DEA 222 order forms properly completed. [893.07, F.S.]			<input type="checkbox"/>	<input type="checkbox"/>			
7	Purchase records for sodium pentobarbital and sodium pentobarbital with lidocaine maintained on premises and separate from administrative records. [64B16-9.004,F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
8	Storage of sodium pentobarbital and sodium pentobarbital with lidocaine and DEA 222's located within a locked room. [64B16-29.005, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
9	Sodium pentobarbital and sodium pentobarbital with lidocaine only being used for euthanizing animals. [64B16-29.003, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
10	Sodium pentobarbital and sodium pentobarbital with lidocaine are the only medical drugs on the premises. [64B16-29.003, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
11	Controlled substance records maintained for 2 years. [21 CFR 1304.04 & 1306.22(b)(3)] & [893.07(4)(b), F.S.]			<input type="checkbox"/>	<input type="checkbox"/>			
12	Shelter administration records show the date of use, identification of the animal, amount of the drug used and the signature of person administering the drug. [64B16-29.004, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
13	Administration and purchase records of the shelter reviewed and signed by on-site manger at least monthly. {64B16-29.004, F.A.C.]			<input type="checkbox"/>	<input type="checkbox"/>			
Remarks:								

**64B16-29.002, F.A.C. General Requirements**

- (1) The applicant shall apply to the Department of Health for a Modified Class II Institutional Pharmacy Permit.
- (2) The applicant shall apply to the Drug Enforcement Administration, Department of Justice, by the appropriate DEA form for Registration as a practitioner, to be designated as "Animal Shelter" on the DEA form.
- (3) The applicant shall be certified by the Board of Pharmacy to the department as having met the requirements of this rule prior to issuance of a permit. The certification process shall require inspection of the facility by authorized person.
- (4) The consultant pharmacist requirements of Section 465.019(5), F.S. are waived as being inapplicable to this special restricted permit.
- (5) Authorized employees of the department shall inspect animal shelters not less than twice per year to determine compliance with this rule.
- (6) Each animal control shelter permittee shall designate an on-site manager of the shelter. The on-site manager and permittee shall notify the department within ten (10) days of any change in the on-site manager of the shelter.

**64 B16-29.003, F.A.C. Drug Requirement**

Animal control shelter permittees are restricted by law to purchase sodium pentobarbital and sodium pentobarbital with lidocaine only for the purpose of euthanizing animals. Federal Schedule II order forms (DEA 222) are required for the purchase of sodium pentobarbital.

**64B16-29.004, F.A.C. Records**

Animal control shelter permittees shall maintain records of purchases and administration of sodium pentobarbital and sodium pentobarbital with lidocaine for a period of no less than two (2) years. Records of administration shall contain:

- (1) the date of use;
- (2) identification of the animal;
- (3) the amount of drug used;
- (4) the signature of the person administering the drug;
- (5) the signature of the on-site manager certifying the accuracy of the records. These records are subject to audit by DEA or authorized department employees to determine adequacy, accuracy, and validity of the record keeping.
- (6) the signature of the on-site manager certifying the accuracy of the records. These records are subject to audit by the Drug Enforcement Administration or authorized employees of the department to determine adequacy, accuracy and validity of the record keeping.

**64B16-29.005,F.A.C. Storage**

Sodium pentobarbital and sodium pentobarbital with lidocaine shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchase of sodium pentobarbital and sodium pentobarbital with lidocaine shall be maintained in a separate file from the records of administration. The records of purchase and administration shall be maintained at the location.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME

ID \_\_\_\_\_

Institutional Representative  
INV 363 Revised 03/11, 01/07, 12/02

Date \_\_\_\_\_

Investigator/Sr. Pharmacist Signature \_\_\_\_\_

**Save**