

# CHAPTER FIVE

## Approved NADAs By FDA File Number

---

The entries in Chapter Five are organized by NADA number in ascending numerical order. For each file number the following information is reported: Brand Name, Sponsor Name, Original Approval Date, Dispensary Status (Rx, OTC, R/O), Route of Administration, Ingredients(s), Species and indications for use, Directions for use including dosages where feasible, Withdrawal Times, reference to the section of 21 CFR in which the approval was codified by FDA, Sponsor Labeler Number, Patents reported by FDA, Exclusivity Periods granted by FDA, and the Pioneer NADA Number if the approval was for a generic product.

Thus the entry:

<b>200-200</b>	<b>HALOTHANE</b>	<b>HALOCARBON LABORATORIES</b>	<b>04/10/1997</b>
STATUS:	RX	ROUTE:	IHL
INGREDIENT(S):	HALOTHANE		
SPECIES:	DOG CAT HORSE MISC: For the induction and maintenance of general anesthesia.		
DIRECTIONS:	Use with accurate vaporizers at 2-5% for induction and 0.5-2% for maintenance. Do not use in pregnant animals.		
WITHDRAWAL:	Not for use in horses intended for food.		
CFR:	21CFR529.1115. Sp# 12164.		
TOLERANCE:	N/A.		
PATENTS:	None reported.		
PIONEER NADA:	014-170		

indicates that NADA 200-200, HALOTHANE, is sponsored by Halocarbon Laboratories, and was approved on 04/10/1997. The product is approved for Rx sale and is to be administered by inhalation. The next line lists the active ingredient, halothane.

The Species header includes the applicable species, followed by the indications for use. The Directions header gives the recommended dosage and treatment pattern and lists selected precautions.

The Withdrawal line gives the pre-slaughter withdrawal time and egg or milk discard time for each species. In the case of halothane this is not applicable because food animals are not to be treated. The CFR line indicates the product is listed in the Code of Federal Regulations at 21CFR529.1115.

The Sponsor Labeler Code is given to help the user quickly find pertinent paragraphs concerning the product in 21 CFR. The Tolerance line lists the established tolerance reference in the CFR and specifies the tolerance levels for muscle, fat, liver, kidney, skin, eggs, milk and the like for various species. Tolerance is not applicable to halothane because it is not for use in food animals. This approval is not entitled to exclusivity and therefore the Exclusivity header does not appear with the entry. This header appears only where needed and will provide the duration of exclusivity and the start date. Finally, this approval was generic and cited pioneer NADA 014-170 for safety and effectiveness.

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

<b>NADA #</b>	<b>BRAND NAME</b>	<b>SPONSOR FIRM</b>	<b>APPROVAL DATE</b>
<b>000-887</b>	<b>FITZSIMMONS LEG PAINT</b>	<b>BIGELOW-CLARK, INC.</b>	<b>05/17/1939</b>
STATUS :	OTC	ROUTE :	TOPICAL
INGREDIENT(S) :	THYMOL, MENTHOL, CAMPHOR, SALICYLIC ACID, METHYL SALICYLATE, CAPSICUM, PINE OIL, ISOPROPANOL, IODINE, ETHER, GLYCERINE		
SPECIES :	HORSE: As a rubefacient-counterirritant with mild blistering properties for treatment of horses exhibiting lameness due to inflammation of the superficial tissues of the leg.		
DIRECTIONS :	Apply to affected area. Do not apply to irritated skin. If excessive irritation develops discontinue use. Avoid contact with eyes and mucous membranes.		
WITHDRAWAL :	Not for use in horses intended for food.		
CFR :	Not codified. Sp# not published.		
TOLERANCE :	N/A.		
PATENTS :	None reported.		
<b>001-363</b>	<b>C.G.P. REINFORCED INJ.</b>	<b>BAYER HEALTHCARE LLC, ANIMAL HEALTH DIV.</b>	<b>09/06/1939</b>
STATUS :	OTC	ROUTE :	INJECTION-IV
INGREDIENT(S) :	CALCIUM GLUCONATE, CALCIUM PYROPHOSPHATE, MAGNESIUM CHLORIDE, DEXTROSE		
SPECIES :	<b>BEEF CATTLE DAIRY CATTLE SWINE SHEEP:</b> For the treatment of calcium, magnesium, phosphorus or glucose deficiencies.		
DIRECTIONS :	Inject slowly and carefully into jugular vein. <b>Cattle:</b> 500 mL/800-1000 lbs. BWT; <b>Sheep and Swine:</b> 50 mL/100 lbs. BWT. Repeat at 8-12 hour intervals as required.		
WITHDRAWAL :	None.		
CFR :	Not codified. Sp# 859.		
TOLERANCE :	None.		
PATENTS :	None reported.		
<b>002-115</b>	<b>N-BUTYL CHLORIDE CAPSULES</b>	<b>H. CLAY GLOVER CO.</b>	<b>01/01/1940</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	N-BUTYL CHLORIDE		
SPECIES :	DOG: For the removal of certain ascarids and hookworms.		
DIRECTIONS :	Dose at 221 mg/1.25 lbs. BWT. Give mild cathartic 30-60 min. after treatment.		
WITHDRAWAL :	N/A.		
CFR :	21CFR520.260. Sp# 10471.		
TOLERANCE :	N/A.		
PATENTS :	None reported.		
<b>004-536</b>	<b>SOMNOPENTYL INJECTION</b>	<b>SCHERING-PLOUGH ANIMAL HEALTH</b>	<b>01/20/1942</b>
STATUS :	RX	ROUTE :	INJECTION-IV, IP
INGREDIENT(S) :	SODIUM PENTOBARBITAL		

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<p>SPECIES: DOG CAT HORSE: For general anesthesia in <b>dogs and cats</b>. For sedation or surgical anesthesia in <b>horses</b>. For the symptomatic treatment of strychnine poisoning in <b>dogs</b>.</p> <p>DIRECTIONS: Product contains 64.8 mg sodium pentobarbital/mL. Administer to effect. For general surgical anesthesia, administer IV 11-13 mg/lb. BWT. For sedation administer 2 mg/lb. BWT. For relieving convulsive seizures in dogs caused by strychnine poisoning, administer to effect. For IP injection give at same dosage level as IV, however results are less uniform. Reduce dose for animals showing undernourishment, toxemia, shock and similar conditions.</p> <p>WITHDRAWAL: Not for use in horses intended for food.</p> <p>CFR: 21CFR522.1704. Sp# 61.</p> <p>TOLERANCE: N/A.</p> <p>PATENTS:</p>			
<b>005-236</b>	<b>SULFODENE</b>	<b>FARNAM COMPANIES, INC.</b>	<b>04/02/1943</b>
STATUS:	OTC	ROUTE:	TOPICAL
INGREDIENT(S): MERCAPTOBENZOTHIAZOLE			
<p>SPECIES: DOG: As an aid in the treatment of hotspots (moist dermatitis) and as first aid for scrapes and abrasions.</p> <p>DIRECTIONS: Apply freely to affected areas twice/day after clipping hair from around lesion and washing with an antiseptic cleanser.</p> <p>WITHDRAWAL: N/A.</p> <p>CFR: 21CFR524.1376. Sp# 17135.</p> <p>TOLERANCE: N/A.</p> <p>PATENTS: None reported.</p>			
<b>005-414</b>	<b>REN-O-SAL FORMULA 75 TABS</b>	<b>ALPHARMA INC.</b>	<b>03/21/1944</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): ROXARSONE			
<p>SPECIES: CHICKEN TURKEY SWINE: <b>Chicken and Turkey</b>: For increased rate of weight gain, improved feed efficiency, and improved pigmentation. <b>Chickens only</b>: as an aid in the prevention of coccidiosis due to <i>E. tenella</i>. <b>Swine only</b>: As an aid in the treatment of swine dysentery (hemorrhagic enteritis or bloody scours).</p> <p>DIRECTIONS: CHICKENS, TURKEYS: Each tablet contains 36 mg roxarsone. For increased rate of weight gain, improved feed efficiency and pigmentation dissolve 2 tablets in each gallon of drinking water (0.002%). Administer continuously throughout growing period. As an aid in the prevention of coccidiosis due to <i>E. tenella</i> <b>in chickens</b> dissolve 8 tablets in each gallon of drinking water and administer for not more than 10 days. <b>Swine</b>: Each tablet contains 400 mg roxarsone. Administer 1 tablet (400 mg) per gallon of drinking water for no more than 6 days or 1 tablet per 2 fl. oz. warm water per 50 lbs BWT as a drench once daily for 1 to 2 days. Treatment may be repeated after 5 days off medication. Use as the sole source of organic arsenic.</p> <p>WITHDRAWAL: 5 Days.</p> <p>CFR: 21CFR520.2088. Sp# 46573.</p> <p>TOLERANCE: 21CFR556.60: 0.5 ppm M, 2 ppm L, K.</p> <p>PATENTS: None reported.</p>			

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<b>005-633</b>	<b>PROTAMONE THYROACTIVE</b>	<b>AGRI-TECH, INC.</b>	<b>02/23/1945</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	IODINATED CASEIN		
SPECIES :	DUCK: For increased rate of weight gain and improved feathering in growing ducks.		
DIRECTIONS :	Type A premix for use in the manufacture of complete duck feed at 100- 200 g/ton.		
WITHDRAWAL :	None.		
CFR :	21CFR558.295. Sp# 17762.		
TOLERANCE :	None.		
PATENTS :	None reported.		
<b>006-019</b>	<b>RUCO POULTRY TABLETS</b>	<b>ALPHARMA INC.</b>	<b>08/30/1946</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	ROXARSONE		
SPECIES :	CHICKEN TURKEY: For improved rate of weight gain, improved feed efficiency and improved pigmentation.		
DIRECTIONS :	Dissolve one 72 mg tablet in each gallon of drinking water (0.002 percent roxarsone). Administer continuously throughout the growing period. Do not administer to chickens producing eggs for human consumption. Use as a sole source of organic arsenic. Overdosage or lack of water intake may result in weakness or paralysis of legs.		
WITHDRAWAL :	5 Days.		
CFR :	21CFR520.2088. Sp# 046573.		
TOLERANCE :	21CFR556.60: 0.5 ppm M, 2 ppm uncooked edible by-products, 0.5 ppm in eggs.		
PATENTS :	None reported.		
<b>006-081</b>	<b>KORUM IMPROVED FORMULA</b>	<b>ALPHARMA INC.</b>	<b>11/14/1946</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	ROXARSONE		
SPECIES :	CHICKEN TURKEY: For improved rate of weight gain , improved feed efficiency and improved pigmentation.		
DIRECTIONS :	Dissolve 1 teaspoon (5 milliliters) in each gallon of drinking water (0.002 percent roxarsone). Administer continuously throughout the growing period. Do not administer to chickens producing eggs for human consumption. Use as the sole source of organic arsenic. Overdosage or lack of water intake may result in weakness or paralysis of legs.		
WITHDRAWAL :	5 Days.		
CFR :	21CFR520.2088. Sp# 046573.		
TOLERANCE :	21CFR556.60: 0.5 ppm M, 2 ppm uncooked edible by-products, 0.5 ppm in eggs.		
PATENTS :	None reported.		

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<b>006-084</b>	<b>SULMET WATER SOLUTION</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>12/02/1946</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) : SULFAMETHAZINE SODIUM			
SPECIES: BEEF CATTLE DAIRY CATTLE SWINE CHICKEN TURKEY: <b>Cattle:</b> For treating bacterial pneumonia, bovine respiratory disease complex, colibacillosis, necrotic pododermatitis, calf diphtheria, acute mastitis and acute metritis. <b>Swine:</b> For treatment of porcine colibacillosis and bacterial pneumonia. <b>Chicken:</b> For control of infectious coryza, coccidiosis, acute fowl cholera and pullorum disease. <b>Turkey:</b> For control of coccidiosis.			
DIRECTIONS : Administer in drinking water to provide: <b>Cattle and Swine:</b> 112.5 mg/lb. BWT/day on first day and 56.25 mg/lb. BWT on subsequent days. <b>Chicken:</b> 61-89 mg/lb. BWT/day. Turkey: 53-130 mg/lb. BWT/day. Product contains a 12.5% solution.			
WITHDRAWAL : Swn: 15 days. Other species: 10 days.			
CFR :	21CFR520.2261a. Sp# 53501.		
TOLERANCE :	21CFR556.670: 0.1 ppm T.		
PATENTS :	None reported.		
<b>006-103</b>	<b>FOLLUTEIN VETERINARY</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>12/19/1946</b>
STATUS :	RX	ROUTE :	INJECTION-IM, IV, IF
INGREDIENT(S) : CHORIONIC GONADOTROPIN			
SPECIES: BEEF CATTLE DAIRY CATTLE: For the treatment of nymphomania due to cystic ovaries.			
DIRECTIONS : Administer 10,000 units IM, 2,500-5,000 units IV or 500- 2,500 units IF. May be repeated in 14 days if necessary. Contains 750 IU/mL in white wax and sesame oil.			
WITHDRAWAL : None.			
CFR :	21CFR522.1081. Sp# 53501.		
TOLERANCE :	None.		
PATENTS :	None reported.		
<b>006-281</b>	<b>INTRAGEL INJECTION</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>08/12/1947</b>
STATUS :	RX	ROUTE :	INJECTION-IV
INGREDIENT(S) : GELATIN			
SPECIES: DOG BEEF CATTLE DAIRY CATTLE SHEEP: For the treatment of shock and to restore circulatory volume and maintain blood pressure.			
DIRECTIONS : Sterile solution containing 8 g gelatin and 0.85% sodium chloride solution/100 mL. Dose should be tailored to the condition of the animal. <b>Small animals:</b> 4-8 mL/lb. BWT; <b>large animals:</b> 2-4 mL/lb. BWT. Administer IV at 10 mL/minute in small animals and 20-30 mL/minute in large animals.			
WITHDRAWAL : None.			
CFR :	21CFR522.1020. Sp# 856.		
TOLERANCE :	None.		
PATENTS :	None reported.		

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<b>006-391</b>	<b>SULFAQUINOXALINE PREMIX</b>	<b>IVX ANIMAL HEALTH</b>	<b>12/19/1947</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	SULFAQUINOXALINE		
SPECIES :	CHICKEN TURKEY RABBIT: As an aid in the prevention of coccidiosis.		
DIRECTIONS :	Type A premix contains 40% SQ. <b>Chickens &amp; Turkeys:</b> For use in the manufacture of poultry feed at levels of 0.015, 0.0175, 0.05 and 0.01%. Do not feed to chickens over 14 weeks of age. Eggs from treated birds are not for human consumption. <b>Rabbits:</b> For use in feed manufacturing at a level of 0.025%.		
WITHDRAWAL :	10 Days.		
CFR :	21CFR558.586. Sp# 59130.		
TOLERANCE :	21CFR556.685: Chickens, turkeys, calves and cattle: 0.1 ppm T.		
PATENTS :	None reported.		
<b>006-417</b>	<b>RECOVR INJECTABLE</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>01/29/1948</b>
STATUS :	RX	ROUTE :	INJECTION-IM, IV
INGREDIENT(S) :	TRIPLENNAMINE HYDROCHLORIDE		
SPECIES :	BEEF CATTLE DAIRY CATTLE HORSE: For use in conditions where antihistaminic therapy may be expected to alleviate some signs of disease.		
DIRECTIONS :	Horse: For intramuscular use only at a dose of 0.5 mg/lb. BWT. Cattle: Administer intravenously or intramuscularly at a dose of 0.5 mg/lb. BWT. Do not use in veal calves.		
WITHDRAWAL :	Cattle: 4 days; milk discard: 24 hrs. Not for use in horses intended for food.		
CFR :	21CFR522.2615. Sp# 53501.		
TOLERANCE :	21CFR556.741: 200 ppb T, 20 ppb milk.		
PATENTS :	None reported.		
<b>006-602</b>	<b>A-H TABLETS</b>	<b>SCHERING-PLOUGH ANIMAL HEALTH</b>	<b>11/16/1948</b>
STATUS :	RX	ROUTE :	ORAL
INGREDIENT(S) :	DOXYLAMINE SUCCINATE		
SPECIES :	DOG CAT HORSE: For use in conditions where antihistaminic therapy may be expected to alleviate some signs of disease.		
DIRECTIONS :	Give as follows: <b>Dog and Cat:</b> 2-3 mg/lb. BWT/day divided in 3-4 doses. <b>Horse:</b> 1-2 mg/lb. BWT/day divided in 3-4 doses. Tablets contain 25 or 100 mg doxylamine succinate.		
WITHDRAWAL :	Not for use in horses intended for food.		
CFR :	21CFR520.784. Sp# 61.		
TOLERANCE :	N/A.		
PATENTS :	None reported.		
<b>006-623</b>	<b>CAPARSOLATE SODIUM</b>	<b>MERIAL LTD.</b>	<b>12/10/1948</b>
STATUS :	RX	ROUTE :	INJECTION-IV
INGREDIENT(S) :	ARSENAMIDE SODIUM		

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<p>SPECIES: DOG: For the prevention and treatment of heartworm disease caused by <i>Dirofilaria immitis</i>.</p> <p>DIRECTIONS: Solution contains 10 mg caparsolate sodium/mL. For treatment give 0.1 mL/lb. BWT twice/day for 2 days. For prevention give 0.1 mL/lb. BWT twice/day at six month intervals in areas where mosquitoes exist year round. Thromboemboli may develop due to dead worms being swept into the pulmonary arteries. Any sign of coughing requires an extended period of restricted activity.</p> <p>WITHDRAWAL: N/A.</p> <p>CFR: 21CFR522.144. Sp# 50604.</p> <p>TOLERANCE: N/A.</p> <p>PATENTS: None reported.</p>			
<b>006-677</b>	<b>S. Q. SOLUTION</b>	<b>IVX ANIMAL HEALTH</b>	<b>01/25/1949</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): SULFAQUINOXALINE SODIUM			
<p>SPECIES: BEEF CATTLE DAIRY CATTLE CHICKEN TURKEY: <b>Cattle:</b> As an aid in the control of coccidiosis caused by organisms susceptible to the drug. <b>Chickens and Turkeys:</b> As an aid in the control of acute fowl cholera and fowl typhoid.</p> <p>DIRECTIONS: Product contains 20 % sulfaquinoxaline sodium solution. Administer at levels of 0.015, 0.025 and 0.04% according to label directions. Not for use in lactating dairy cattle. Not for use in birds laying eggs for human consumption.</p> <p>WITHDRAWAL: 10 Days.</p> <p>CFR: Not codified. Sp# 59130.</p> <p>TOLERANCE: 21CFR556.685: Chickens, turkeys, calves and cattle: 0.1 ppm T.</p> <p>PATENTS: None reported.</p>			
<b>006-691</b>	<b>VERMIPLEX CAPSULES</b>	<b>SCHERING-PLOUGH ANIMAL HEALTH</b>	<b>02/07/1949</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): DICHLOROPHENE, TOLUENE			
<p>SPECIES: DOG CAT: For the removal of ascarids, hookworms and as an aid in the removal of tapeworms.</p> <p>DIRECTIONS: Dose at rate of 100 mg dichlorophene and 120 mg toluene/lb. BWT. Withhold solid food and milk for 12 hours prior to and 4 hours after treatment.</p> <p>WITHDRAWAL: N/A.</p> <p>CFR: 21CFR520.580. Sp# 61.</p> <p>TOLERANCE: N/A.</p> <p>PATENTS: None reported.</p>			
<b>006-707</b>	<b>SULQUIN 6-50 LIQUID</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>02/14/1949</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): SULFAQUINOXALINE SODIUM			

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
	<p>SPECIES: CHICKEN TURKEY: <b>Chicken:</b> For control of coccidiosis (<i>Eimeria tenella</i>, <i>E. necatrix</i>, <i>E. acervulina</i>, <i>E. maxima</i>, <i>E. brunetti</i>). <b>Turkey:</b> As an aid in the control of outbreaks of coccidiosis (<i>E. meleagriditis</i>, <i>E. adenoides</i>). <b>Chicken and Turkey:</b> As an aid in the control of acute fowl cholera (<i>Pasteurella multocida</i>), for control of fowl typhoid (<i>Salmonella gallinarum</i>) caused by organisms susceptible to sulfaquinoxaline.</p> <p>DIRECTIONS : Solution contains 28.62% sulfaquinoxaline sodium for use in making 0.025% or 0.04% solution for use in the drinking water. <b>Chickens:</b> For coccidiosis, give 0.04% for 2-3 days, skip 3 days then give 0.025% for 2 more days. If bloody droppings appear, repeat treatment at 0.025% level for 2 more days. <b>Turkeys:</b> For coccidiosis, give 0.025% for 2-3 days, skip 3 days, give for 2 days, skip 3 days, give for 2 days, skip 3 days, give 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mash. <b>Chickens and Turkeys:</b> For fowl typhoid and acute fowl cholera, give 0.04% for 2-3 days. Move birds to clean ground. If disease recurs, repeat treatment. Not for use in poultry producing eggs for human consumption.</p> <p>WITHDRAWAL : 10 Days.</p> <p>CFR : 21CFR520.2325a. Sp# 53501.</p> <p>TOLERANCE : 21CFR556.685: Chickens, turkeys: 0.1 ppm T.</p> <p>PATENTS : None reported.</p>		
<b>006-891</b>	<b>LIQUID SUL-Q-NOX</b>	<b>ALPHARMA INC.</b>	<b>04/28/1949</b>
	STATUS : OTC	ROUTE : ORAL	
	INGREDIENT(S) : SULFAQUINOXALINE SODIUM		
	<p>SPECIES: BEEF CATTLE CHICKEN TURKEY: <b>Chicken:</b> As an aid in the control of outbreaks of coccidiosis caused by <i>Eimeria tenella</i>, <i>E. necatrix</i>, <i>E. acervulina</i>, <i>E. maxima</i>, and <i>E. brunetti</i>. <b>Turkeys:</b> As an aid in the control of outbreaks of coccidiosis caused by <i>E. meleagriditis</i> and <i>E. adenoides</i>. <b>Chickens and turkeys:</b> As an aid in the control of acute fowl cholera caused by <i>Pasteurella multocida</i> susceptible to sulfaquinoxaline and fowl typhoid caused by <i>Salmonella gallinarum</i> susceptible to sulfaquinoxaline. <b>Calves and cattle:</b> For the control and treatment of outbreaks of coccidiosis caused by <i>E. bovis</i> or <i>E. zurnii</i>.</p> <p>DIRECTIONS : Product is a 31.92 % sulfaquinoxaline solution (sodium and potassium salts). <b>Chickens:</b> Administer at the 0.04% level in drinking water for 2 or 3 days, skip 3 days then administer at the 0.025% level for 2 more days. If bloody droppings appear, repeat treatment at the 0.025% level for 2 more days. Do not change litter unless absolutely necessary. Do not give flushing mash. <b>Turkeys:</b> Administer at the 0.025% level in drinking water for 2 days, skip 3 days, give for 2 days, skip 3 days and give for 2 more days. Repeat if necessary. Do not change litter unless absolutely necessary. Do not give flushing mash. As an aid in the control of fowl cholera in chickens and turkeys administer at the 0.04% level for 2 or 3 days. Move birds to clean ground. If disease recurs, repeat treatment. <b>Cattle and calves:</b> Administer at the 0.015% level for 3 to 5 days in drinking water. Do not feed to chickens laying eggs for human consumption. Do not use in calves to be processed for veal.</p> <p>WITHDRAWAL : All species: 10 Days. Not for use in preruminating or veal calves.</p> <p>CFR : 21CFR520.2325a. Sp# 46573.</p> <p>TOLERANCE : 21CFR556.685: Chickens, turkeys, calves and cattle: 0.1 ppm T.</p> <p>PATENTS : None reported.</p>		
<b>006-983</b>	<b>A-H INJECTION</b>	<b>SCHERING-PLOUGH ANIMAL HEALTH</b>	<b>04/17/1950</b>
	STATUS : RX	ROUTE : INJECTION-IV, IM, SC	
	INGREDIENT(S) : DOXYLAMINE SUCCINATE		

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<p>SPECIES: DOG CAT HORSE: For use in conditions where antihistaminic therapy may be expected to alleviate some sign of disease.</p> <p>DIRECTIONS: <b>Dog and Cat:</b> Inject IM or SC in divided injection sites at 0.5-1.0 mg/lb. BWT. <b>Horse:</b> Inject IM or SC in divided injection sites or inject slowly IV at 25 mg/100 lbs. BWT. Dose may be repeated in 8-12 hours if necessary. Solution contains 11.36 mg doxylamine succinate/mL.</p> <p>WITHDRAWAL: Not for use in horses intended for food.</p> <p>CFR: 21CFR522.784. Sp# 61.</p> <p>TOLERANCE: N/A.</p> <p>PATENTS: None reported.</p>			
<b>007-076</b>	<b>SULFA-NOX LIQUID</b>	<b>VIRBAC AH, INC.</b>	<b>11/09/1949</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): SULFAQUINOXALINE SODIUM			
<p>SPECIES: CHICKEN TURKEY BEEF CATTLE DAIRY CATTLE: <b>Chicken:</b> For control of coccidiosis (<i>Eimeria tenella</i>, <i>E. necatrix</i>, <i>E. acervulina</i>, <i>E. maxima</i>, <i>E. brunetti</i>). <b>Turkey:</b> For control of coccidiosis (<i>E. meleagritidis</i>, <i>E. adenoides</i>). <b>Chicken and Turkey:</b> For control of acute fowl cholera (<i>Pasteurella multocida</i>), for control of fowl typhoid (<i>Salmonella gallinarum</i>). <b>Cattle:</b> For the treatment and control of coccidiosis (<i>Eimeria bovis</i>, <i>E. zurnii</i>).</p> <p>DIRECTIONS: A solution containing 3.44% sulfaquinoxaline for use in drinking water. <b>Chicken:</b> For coccidiosis, give 0.04% for 2-3 days, skip 3 days then give 0.025% for 2 more days. <b>Turkey:</b> For coccidiosis, give 0.025% for 2-3 days, skip 3 days, give for 2 days, skip 3 days, give for 2 days, skip 3 days, give 2 more days. <b>Poultry:</b> For fowl typhoid and acute fowl cholera, give 0.04% for 2-3 days. <b>Cattle:</b> Give 0.015% for 2-3 days. Not for use in lactating dairy cattle. Not for use in poultry producing eggs for human consumption.</p> <p>WITHDRAWAL: 10 Days.</p> <p>CFR: 21CFR520.2325a. Sp# 51311.</p> <p>TOLERANCE: 21CFR556.685: Chickens, turkeys, calves and cattle: 0.1 ppm T.</p> <p>PATENTS: None reported.</p>			
<b>007-087</b>	<b>SULFAQUINOXALINE POWDER</b>	<b>IVX ANIMAL HEALTH</b>	<b>11/18/1949</b>
STATUS:	OTC	ROUTE:	ORAL
INGREDIENT(S): SULFAQUINOXALINE SODIUM			
<p>SPECIES: CHICKEN TURKEY BEEF CATTLE DAIRY CATTLE: <b>Chicken and Turkey:</b> As an aid in the prevention of coccidiosis, as an aid in the control of acute fowl cholera and acute fowl typhoid. <b>Cattle:</b> For the control and treatment of outbreaks of coccidiosis.</p> <p>DIRECTIONS: A 25% soluble powder for use in drinking water. Recommended dosage provides 10-45 mg/lb. BWT/day <b>in chickens</b>, 3.5-55 mg/lb. BWT/day <b>in turkeys</b> and 6 mg/lb. BWT/day <b>in cattle and calves</b> depending on the age, class of animal, ambient temperature and other factors. Make fresh drinking water solution daily. Not for use in lactating dairy cattle. Not for use in chickens and turkeys producing eggs for human consumption.</p> <p>WITHDRAWAL: 10 Days.</p> <p>CFR: 21CFR520.2325a. Sp# 59130.</p> <p>TOLERANCE: 21CFR556.685: Chickens, turkeys, calves and cattle: 0.1 ppm T.</p>			

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
PATENTS : None reported.			
<b>007-616</b>	<b>HISTOSTAT-50 PREMIX</b>	<b>ALPHARMA INC.</b>	<b>12/08/1950</b>
STATUS : OTC ROUTE : ORAL			
INGREDIENT(S) : NITARSONE			
SPECIES: CHICKEN TURKEY: As an aid in the prevention of blackhead (histomoniasis).			
DIRECTIONS : A 50% nitarsonone Type A premix for use in the manufacture of complete poultry feeds at 0.01875% nitarsonone. Drug is not effective in preventing blackhead in birds infected more than 4-5 days. Use as sole source of organic arsenic. Provide adequate drinking water at all times. Overdosage or lack of water may result in leg weakness or paralysis. The drug is dangerous for ducks, geese and dogs.			
WITHDRAWAL : 5 Days.			
CFR : 21CFR558.369. Sp# 46573.			
TOLERANCE : 21CFR556.60: 0.5 ppm M, Eggs, 2 ppm L, K.			
PATENTS : None reported.			
<b>007-829</b>	<b>TAPEWORM TABLETS</b>	<b>HAPPY JACK, INC.</b>	<b>02/15/1980</b>
STATUS : OTC ROUTE : ORAL			
INGREDIENT(S) : DICHLOROPHENE			
SPECIES: DOG: For the removal of tapeworms ( <i>Taenia pisiformis</i> and <i>Dipylidium caninum</i> ).			
DIRECTIONS : Give single dose of 1 tablet (1 g dichlorophene)/10 lbs. BWT. Withhold solid food and milk for at least 12 hours before and 4 hours after treatment.			
WITHDRAWAL : N/A.			
CFR : 21CFR520.581. Sp# 23851.			
TOLERANCE : N/A.			
PATENTS : None reported.			
<b>007-879</b>	<b>TERRAMYCIN VET CAPSULES</b>	<b>PFIZER, INC.</b>	<b>02/21/1951</b>
STATUS : RX ROUTE : ORAL			
INGREDIENT(S) : OXYTETRACYCLINE HYDROCHLORIDE			
SPECIES: DOG CAT: For the treatment of bacterial pneumonia, tonsillitis, bacterial enteritis, urinary tract infections and wound infections caused by organisms susceptible to oxytetracycline.			
DIRECTIONS : Capsule contains 125 or 250 mg oxytetracycline. Give 25-50 mg/lb. BWT/day in divided doses at 12 hour intervals. Continue until 48 hours after symptoms subside. If no improvement is seen in 48-72 hours, re-evaluate diagnosis and therapy.			
WITHDRAWAL : N/A.			
CFR : 21CFR520.1660b. Sp# 69.			
TOLERANCE : N/A.			
PATENTS : None reported.			

**CHAPTER FIVE**  
**APPROVED NEW ANIMAL DRUGS BY NADA NUMBER**

NADA #	BRAND NAME	SPONSOR FIRM	APPROVAL DATE
<b>007-891</b>	<b>3-NITRO PREMIX</b>	<b>ALPHARMA INC.</b>	<b>03/23/1951</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	ROXARSONE		
SPECIES :	SWINE CHICKEN TURKEY: For increased rate of weight gain, improved feed efficiency and improved pigmentation in poultry. For increased rate of weight gain and feed efficiency and for the treatment of dysentery in swine.		
DIRECTIONS :	A 10, 20, 50 or 80% Type A premix for use in the manufacture of complete animal feeds. For increased rate of weight gain, improved feed efficiency and improved pigmentation <b>in chickens and turkeys</b> provide 22.7-45.4 g/ton. Use as sole source of arsenic. Overdosage or lack of water may cause leg weakness. <b>For swine</b> give 22.7-34.1 g/ton for increased rate of weight gain and improved feed efficiency. For treatment of swine dysentery, give 181.5 g/ton. Feed for not more than 6 consecutive days. If no improvement is observed, consult veterinarian.		
WITHDRAWAL :	5 Days.		
CFR :	21CFR558.530. Sp# 46573.		
TOLERANCE :	21CFR556.60: 0.5 ppm M, Eggs; 2 ppm L, K, F, S.		
PATENTS :	None reported.		
<b>007-981</b>	<b>SOXISOL TABLETS</b>	<b>FORT DODGE ANIMAL HEALTH, DIV. OF WYETH</b>	<b>05/07/1951</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	SULFISOXAZOLE		
SPECIES :	DOG CAT: As an aid in the treatment of bacterial enteritis and bacterial pneumonia caused by organisms sensitive to sulfisoxazole.		
DIRECTIONS :	Administer orally 1 tablet/4 lbs. BWT. Repeat dosage at 24 hour intervals until 2-3 days after animal is asymptomatic. Provide adequate supply of drinking water. If symptoms persist after 2-3 days, consult a veterinarian. Contains 250 mg sulfisoxazole/tablet.		
WITHDRAWAL :	N/A.		
CFR :	21CFR520.2330. Sp# 856.		
TOLERANCE :	N/A.		
PATENTS :	None reported.		
<b>008-019</b>	<b>PRO-GEN PLUS PREMIX</b>	<b>FLEMING LABORATORIES, INC.</b>	<b>05/11/1951</b>
STATUS :	OTC	ROUTE :	ORAL
INGREDIENT(S) :	ARSANILIC ACID		
SPECIES :	SWINE CHICKEN TURKEY: <b>Chicken and Turkey:</b> For growth promotion and feed efficiency; improving pigmentation, or increased egg production and feed efficiency. <b>Swine:</b> For increased rate of weight gain and feed efficiency at 45 to 90 g/ton and as an aid in control of swine dysentery (hemorrhagic enteritis, bloody dysentery) at 90 g/ton in swine.		
DIRECTIONS :	Type A premix containing 20, 50 or 100 % AA for use in the manufacture of Type C medicated animal feeds to contain 45 to 90 g/ton. Use as the sole source of arsenic.		
WITHDRAWAL :	5 Days.		
CFR :	21CFR558.62. Sp# 15565.		