NADA/ANADA	Ingredient new animal drugs
107–997	Roxarsone/NICARB (nicarbazin)/LINCOMIX (lincomycin).
108–115	Roxarsone/NICARB (nicarbazin).
120–724	3–NITRO (roxarsone)/STAFAC (virginiamycin)/COBAN (monensin).
138–953	3–NITRO (roxarsone)/STAFAC (virginiamycin)/BIO–COX (salinomycin).
141–058	3–NITRO (roxarsone)/AVIAX (semduramycin)/BMD (bacitracin MD).
141–066	3–NITRO (roxarsone)/AVIAX (semduramycin).
141–226	Roxarsone/AVIAX (semduramycin)/STAFAC (virginiamycin).
200–170	3–NITRO (roxarsone)/NICARMIX 25 (nicarbazin)/LINCOMIX (lincomycin).
200–172	3–NITRO (roxarsone)/NICARMIX 25 (nicarbazin).

• Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the following four NADAs:

NADA	Ingredient new animal drugs
041–500	3–NITRO (roxarsone)/COBAN (monensin).
049–464	Roxarsone/monensin/bacitracin.
140–445	Roxarsone/MONTEBAN (narasin).
141–113	3–NITRO (roxarsone)/MAXIBAN (narasin and nicarbazin).

• Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland, has requested that FDA withdraw approval of the following three NADAs:

NADA	Ingredient new animal drugs
038–241	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin)/zoalene.
038–242	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin)/amprolium and ethopabate.
038–624	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin).

• Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144 has requested that FDA withdraw approval of the following ANADA:

ANADA	Ingredient new animal drugs
200–355	3–NITRO (roxarsone)/PENNCHLOR (chlortetracycline)/BIO–COX (salinomycin).

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 *Notice of withdrawal of approval of application,* notice is given that approval of the NADAs and ANADAs listed in this document, and all supplements and amendments thereto, is hereby withdrawn, effective March 10, 2014.

Elsewhere in this issue of the **Federal Register,** FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: February 3, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–02616 Filed 2–26–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA–2014–N–0002]

Zoetis Inc., et al.; Withdrawal of Approval of New Animal Drug Applications for Combination Drug Medicated Feeds Containing an Arsenical Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of 69 new animal drug applications (NADAs) and 22 abbreviated new animal drug applications (ANADAs) for use of arsanilic acid, carbarsone, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds. This action is being taken at the sponsor's request because the products are no longer manufactured or marketed. FDA is also amending the animal drug regulations to remove entries describing conditions of use for combination drug medicated feeds for which no NADA is approved. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective March 10, 2014.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, *john.bartkowiak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Recently, the Agency provided notice of the withdrawal of approval of NADAs for Type A medicated articles containing

arsanilic acid, carbarsone, and roxarsone and revoked applicable regulations for their conditions of use to manufacture single-ingredient medicated feeds in 21 CFR part 558 *New Animal Drugs For Use in Animal Feeds* (78 FR 70062, Nov. 22, 2013; 78 FR 69992, Nov. 22, 2013; 78 FR 70566, Nov. 26, 2013; 78 FR 70496, Nov. 26, 2013).

Subsequently, the following six sponsors of NADAs and ANADAs permitting use of arsanilic acid, carbarsone, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds requested that FDA withdraw approval of their applications because these combination medicated feeds are no longer manufactured or marketed.

- Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following 39 NADAs and 11 ANADAs:

NADA/ANADA	Ingredient new animal drugs
040–435	3–NITRO (roxarsone)/DECCOX (decoquinate).
041–178	Roxarsone/AMPROL Plus (amprolium and ethopabate)/LINCOMIX (lincomycin).
041–984	Roxarsone/ROFENAID (sulfadimethoxine/ormetoprim).
091–326	3–NITRO (roxarsone)/DECCOX (decoquinate)/ALBAC (bacitracin zinc).
092–522	Roxarsone/COBAN (monensin)/LINCOMIX (lincomycin).
095–546	Roxarsone/ROBENZ (robenidine).
102–485	3–NITRO (roxarsone)/AVATEC (lasalocid).
105–758	3–NITRO (roxarsone)/AMPROL HI–E (amprolium and ethopabate)/BACIFERM (bacitracin zinc).
112–661	3–NITRO (roxarsone)/AVATEC (lasalocid)/LINCOMIX (lincomycin).
112–687	3–NITRO (roxarsone)/AVATEC (lasalocid)/FLAVOMYCIN (bambermycins).
116–082	3–NITRO (roxarsone)/AVATEC (lasalocid)/BMD (bacitracin MD).
116–088	3–NITRO (roxarsone)/COBAN (monensin)/BMD (bacitracin MD).
123–154	3–NITRO (roxarsone)/BACIFERM (bacitracin zinc)/COBAN (monensin).
126–052	3–NITRO (roxarsone)/AVATEC (lasalocid)/BACIFERM (bacitracin zinc).
131–894	3–NITRO (roxarsone)/AVATEC (lasalocid)/bacitracin MD.
132–447	Roxarsone/BIO–COX (salinomycin).
134–185	3–NITRO (roxarsone)/BIO–COX (salinomycin)/FLAVOMYCIN (bambermycins).
135–321	3–NITRO (roxarsone)/BIO–COX (salinomycin)/BMD (bacitracin MD).
137–536	3–NITRO (roxarsone)/BIO–COX/ALBAC (bacitracin zinc).
138–703	3–NITRO (roxarsone)/COBAN (monensin)/ALBAC (bacitracin zinc).
139–190	3–NITRO (roxarsone)/BIO–COX (salinomycin)/BACIFERM (bacitracin zinc).
140–581	3–NITRO (roxarsone)/BIO–COX (salinomycin)/LINCOMIX (lincomycin).
140–852	3–NITRO (roxarsone)/MONTEBAN/BMD (bacitracin MD).
140–867	3–NITRO (roxarsone)/BIO–COX (salinomycin)/AUREOMYCIN (chlortetracycline).
141–100	3–NITRO (roxarsone)/DECCOX (decoquinate)/BMD (bacitracin MD).
141–112	3–NITRO (roxarsone)/MAXIBAN (narasin and nicarbazin)/BMD (bacitracin MD).
141–121	3–NITRO (roxarsone)/BIO–COX (salinomycin)/BMD (bacitracin MD).
141–131	3–NITRO (roxarsone)/ZOAMIX (zoalene)/BMD (bacitracin MD).
141–135	3–NITRO (roxarsone)/BIO–COX (salinomycin).
141–138	3–NITRO (roxarsone)/COBAN (monensin)/BMD (bacitracin MD).
141–139	3–NITRO (roxarsone)/COBAN (monensin).
141–142	3–NITRO (roxarsone)/AMPROL (amprolium)/BMD (bacitracin MD).
141–155	3–NITRO (roxarsone)/ROBENZ (robenidine)/BMD (bacitracin MD).
141–157	3–NITRO (roxarsone)/STENOROL (halofuginone).
141–223	3–NITRO (roxarsone)/CLINACOX (diclazuril).
141–293	3–NITRO (roxarsone)/AVATEC (lasalocid).
200–206	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/DECCOX (decoquinate).
200–207	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/COYDEN 25 (clopidol).
200–208	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/AVATEC (lasalocid).
200–209	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/SACOX (salinomycin).
200–214	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/AMPROL HI–E (amprolium and ethopabate).
200–211	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/COBAN (monensin).
200–215	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/BIO–COX (salinomycin).
200–217	3–NITRO (roxarsone)/ALBAC (bacitracin zinc)/AMPROL HI–E (amprolium and ethopabate).
200–259	3–NITRO (roxarsone)/SACOX (salinomycin)/CHLORMAX (chlortetracycline).
200–260	3–NITRO (roxarsone)/BIO–COX (salinomycin)/CHLORMAX (chlortetracycline).
038–879	CARB–O–SEP (carbarsone)/ZOAMIX (zoalene).
039–646	CARB–O–GAIN (carbarsone)/BMD (bacitracin MD).
136–484	CARB–O–SEP (carbarsone)/BACIFERM (bacitracin zinc).
200–203	CARB–O–SEP (carbarsone)/ALBAC (bacitracin zinc).

- Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria, has requested that FDA withdraw approval of the following 16 NADAs and 8 ANADAs:

NADA/ANADA	Ingredient new animal drugs
013–461	3–NITRO (roxarsone)/AMPROL Plus (amprolium and ethopabate).
040–264	3–NITRO (roxarsone)/COYDEN 25 (clopidol).
041–541	3–NITRO (roxarsone)/COYDEN 25 (clopidol)/BMD (bacitracin MD).
044–016	Roxarsone + bacitracin Zinc/COYDEN 25 (clopidol).

NADA/ANADA	Ingredient new animal drugs
049–179	Roxarsone/AMPROL HI–E (amprolium and ethopabate).
049–180	Roxarsone/AMPROL HI–E (amprolium and ethopabate)/BMD (bacitracin MD).
095–547	3–NITRO (roxarsone)/AMPROL HI–E (amprolium and ethopabate)/FLAVOMYCIN (bambermycins).
095–548	3–NITRO (roxarsone)/AMPROL (amprolium)/FLAVOMYCIN (bambermycins).
095–549	3–NITRO (roxarsone)/AMPROL (amprolium)/FLAVOMYCIN (bambermycins).
098–341	3–NITRO (roxarsone)/COBAN (monensin)/FLAVOMYCIN (bambermycins).
101–628	3–NITRO (roxarsone)/FLAVOMYCIN (bambermycins)/zoalene.
140–533	3–NITRO (roxarsone)/STENOROL (halofuginone)/BMD (bacitracin MD).
140–843	3–NITRO (roxarsone)/MONTEBAN (narasin)/FLAVOMYCIN (bambermycins).
141–190	3–NITRO (roxarsone)/LINICOX (diclazuril)/BMD (bacitracin MD).
200–080	3–NITRO (roxarsone)/SACOX (salinomycin)/FLAVOMYCIN (bambermycins).
200–081	3–NITRO (roxarsone)/SACOX (salinomycin)/BMD (bacitracin MD).
200–086	3–NITRO (roxarsone)/SACOX (salinomycin)/ALBAC (bacitracin zinc).
200–090	3–NITRO (roxarsone)/SACOX (salinomycin)/LINCOMIX (lincomycin).
200–091	3–NITRO (roxarsone)/SACOX (salinomycin)/AUREOMYCIN (chlortetracycline).
200–094	3–NITRO (roxarsone)/SACOX (salinomycin)/STAFAC (virginiamycin).
200–097	3–NITRO (roxarsone)/SACOX (salinomycin).
200–143	3–NITRO (roxarsone)/SACOX (salinomycin)/BACIFERM (bacitracin zinc).
118–507	CARB–O–SEP (carbarsone)/AMPROL (amprolium).
130–661	CARB–O–SEP (carbarsone)/FLAVOMYCIN (bambermycins).

• Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666 has requested that FDA withdraw approval of the following seven NADAs and two ANADAs:

NADA/ANADA	Ingredient new animal drugs
107–997	Roxarsone/NICARB (nicarbazin)/LINCOMIX (lincomycin).
108–115	Roxarsone/NICARB (nicarbazin).
120–724	3–NITRO (roxarsone)/STAFAC (virginiamycin)/COBAN (monensin).
138–953	3–NITRO (roxarsone)/STAFAC (virginiamycin)/BIO–COX (salinomycin).
141–058	3–NITRO (roxarsone)/AVIAX (semduramycin)/BMD (bacitracin MD).
141–066	3–NITRO (roxarsone)/AVIAX (semduramycin).
141–226	Roxarsone/AVIAX (semduramycin)/STAFAC (virginiamycin).
200–170	3–NITRO (roxarsone)/NICARMIX 25 (nicarbazin)/LINCOMIX (lincomycin).
200–172	3–NITRO (roxarsone)/NICARMIX 25 (nicarbazin).

• Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the following four NADAs:

NADA	Ingredient new animal drugs
041–500	3–NITRO (roxarsone)/COBAN (monensin).
049–464	Roxarsone/monensin/bacitracin.
140–445	Roxarsone/MONTEBAN (narasin).
141–113	3–NITRO (roxarsone)/MAXIBAN (narasin and nicarbazin).

• Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, has requested that FDA withdraw approval of the following three NADAs:

NADA	Ingredient new animal drugs
038–241	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin)/zoalene.
038–242	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin)/amprolium + ethopabate.
038–624	PRO–GEN (arsanilic acid)/ERYTHRO (erythromycin).

• Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144 has requested that FDA withdraw approval of the following ANADA:

NADA	Ingredient new animal drugs
200–355	3–NITRO (roxarsone)/PENNCHLOR (chlortetracycline)/BIO–COX (salinomycin).

Elsewhere in this issue of the **Federal Register,** FDA gave notice that approval of these NADAs and ANADAs, and all supplements and amendments thereto, is withdrawn, effective March 10, 2014. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

In addition, FDA has noticed that certain sections in part 558 contain entries describing conditions of use for combination drug medicated feeds for which no NADA is approved. These errors were introduced by the Agency during the 1976 recodification of certain food additive regulations (41 FR 10984, March 15, 1976). That rule did not identify whether particular regulations were the subject of an approved NADA and consequently resulted in codification of certain conditions of use for which there is no approved NADA. At this time, the Agency is amending the regulations to remove entries that describe conditions of use for combination drug medicated feeds for which no NADA is approved. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Parts 556

Animal drugs, Food.

21 CFR Parts 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 2. Revise § 556.60 to read as follows:

§ 556.60 Arsenic.

(a) [Reserved]

(b) *Tolerances.* The tolerances for total residue of combined arsenic (calculated as As) are:

(1) *Turkeys*—(i) *Muscle and eggs:* 0.5 parts per million (ppm).

(ii) *Other edible tissues:* 2 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.369 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.4 [Amended]

■ 4. In § 558.4, in paragraph (d), in the ''Category II'' table:

■ a. Remove the entries for ''Arsanilate acid'', ''Carbarsone'', and ''Sulfaquinoxaline'';

■ b. Remove the row entries under ''Nitarsone'' for ''Sulfanitran'' and ''Roxarsone''.

■ c. Remove the four entries for ''Roxarsone'' and their respective following row entries; and

■ d. In the fourth entry for ''Sulfamethazine,'' remove its three following row entries for ''Aklomide'' and two following row entries for ''Roxarsone''.

■ 5. In § 558.55, revise paragraphs (d)(1) through (3) and add paragraph (d)(4) to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(1) *Cattle.* It is used as follows:

Amprolium in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 11, 350; to provide 5 milligrams per kilogram of body weight per day.	Calves: As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Top-dress on or mix in the daily ration. Feed for 21 days when experience indicates that coccidiosis is likely to be a hazard, as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592
(ii) 113.5 to 11, 350; to provide 10 milligrams per kilogram of body weight per day.	Calves: As an aid in the treatment of coccidiosis caused by *Eimeria bovis* and *E. zuernii.*	Top-dress on or mix in the daily ration. Feed for 5 days as the sole source of amprolium. Withdraw 24 hours before slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.	016592

(2) *Chickens.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	.....	Replacement chickens: For development of active immunity to coccidiosis.	Feed continuously until onset of production as follows:	016592

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5	54.5–113.5	36.3–113.5

Growing conditions	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Amprolium in grams per ton	Amprolium in grams per ton	Amprolium in grams per ton
Slight exposure to coccidiosis	(0.008%–0.0125%) 36.3–113.5 (0.004%–0.0125%)	(0.006%–0.0125%) 36.3–113.5 (0.004%–0.0125%)	(0.004%–0.0125%) 36.3–113.5 (0.004%–0.0125%)

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3 to 113.5	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed according to subtable in item (i). Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 72.6 to 113.5		Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella* only.	Feed continuously as the sole ration; as sole source of amprolium.	016592
(iv) 72.6 to 113.5	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella* only; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(v) 113.5		1. Laying chickens: For prevention of coccidiosis. 2. Laying chickens: For treatment of coccidiosis in moderate outbreaks.	Feed continuously as the sole ration; as the sole source of amprolium. Feed for 2 weeks.	016592
(vi) 113.5 to 227		1. Replacement chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired. 2. Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired.	Feed continuously from day-old until onset of production; as the sole source of amprolium. Feed continuously as the sole ration; as sole source of amprolium.	016592
(vii) 113.5 to 227	Bambermycins 1 to 2.	Broiler chickens: For prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(viii) 227		Laying chickens: For treatment of coccidiosis in severe outbreaks..	Feed for 2 weeks	016592

(3) *Turkeys.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5	Bambermycins 1 to 4.	Growing turkeys: For prevention of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole source of amprolium; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(ii) 113.5 to 227		Turkeys: For prevention of coccidiosis	Feed continuously as the sole ration; as sole source of amprolium.	016592

(4) *Pheasants.* It is used as follows:

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 159		Growing pheasants: For the prevention of coccidiosis caused by *Eimeria colchici, E. duodenalis,* and *E. phasiani*.	Feed continuously as sole ration. Use as sole source of amprolium.	016592
(ii) [Reserved]				

■ 6. In § 558.58, revise paragraph (e) to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(e) *Conditions of use.* It is used in chicken feed as follows:

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(1) Amprolium 113.5 and ethopabate 3.6.	.....	Broiler chickens: As an aid in the prevention of coccidiosis.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens.	016592
(2) Amprolium 113.5 and ethopabate 3.6.	Lincomycin 2 to 4	Broiler chickens: As an aid in the prevention of coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration; as sole source of amprolium. Not for laying chickens. Lincomycin as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(3) Amprolium 113.5 and ethopabate 36.3.	.....	Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur.	Feed continuously as sole ration; as sole source of amprolium. Not for chickens over 16 weeks of age.	016592
(4) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50	1. Broiler chickens and replacement chickens: where immunity to coccidiosis is not desired; to aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.	Feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis. Bacitracin as bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592
(5) Amprolium 113.5 and ethopabate 36.3.	Bacitracin 4 to 50	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for improved feed efficiency.	Feed as the sole ration from the time chickens are placed on litter until market weight. Not for chickens over 16 weeks of age; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for coccidiosis. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(6) Amprolium 113.5 and ethopabate 3.6.	Bambermycins 1 to 3.	Broiler chickens: As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain, improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(7) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 15	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(8) Amprolium 113.5 and ethopabate 36.3.	Virginiamycin 5 to 15.	Broiler chickens; as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti* is likely to occur; for increased rate of weight gain.	Feed continuously as the sole ration; as sole source of amprolium. Do not feed to laying chickens. Not for chickens over 16 weeks of age. Virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(9) Amprolium 227 and ethopabate 3.6.	.....	For broiler chickens and replacement chickens where immunity to coccidiosis is not desired; prevention of coccidiosis.	Not for laying chickens	016592
(10) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 100 to 200.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption. Feed for 7 to 14 days.	054771
(11) Amprolium 227 and ethopabate 3.6.	Chlortetracycline 200 to 400.	For chickens where immunity to coccidiosis is not desired; prevention of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	In low calcium feed containing 0.8% dietary calcium and 1.5% sodium sulfate; feed continuously as sole ration for 7 to 14 days; do not feed to chickens producing eggs for human consumption.	054771

§ 558.62 [Removed]

■ 7. Remove § 558.62.

■ 8. In § 558.76, revise paragraph (d)(3) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) Bacitracin methylene disalicylate may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Decoquinate as in § 558.195.

(iv) Diclazuril as in § 558.198.

(v) Fenbendazole as in § 588.258.

(vi) Halofuginone as in § 558.265.

(vii) Hygromycin B as in § 588.274.

(viii) Ivermectin as in § 558.300.

(ix) Lasalocid sodium as in § 558.311.

(x) Monensin as in § 588.355.

(xi) Narasin as in § 558.363.

(xii) Nicarbazin alone and with narasin as in § 558.366.

(xiii) Nitarsone as in § 558.369.

(xiv) Robenidine as in § 558.515.

(xv) Salinomycin as in § 558.550.

(xvi) Semduramicin as in § 558.555.

(xvii) Zoalene as in § 558.680.

■ 9. In § 558.78, revise paragraph (d)(3) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) Bacitracin zinc may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Clopidol as in § 558.175.

(iii) Decoquinate as in § 558.195.

(iv) Lasalocid as in § 558.311.

(v) Monensin as in § 558.355.

(vi) Naracin as in § 558.363.

(vii) Nitarsone as in § 558.369.

(viii) Robenidine as in § 558.515.

(ix) Salinomycin as in § 558.550.

■ 10. In § 558.95, revise paragraph (d)(5) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) Bambermycins may also be used in combination with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Clopidal as in § 558.175.

(iv) Diclazuril as in § 558.198.

(v) Halofuginone as in § 558.265.

(vi) Lasalocid as in § 558.311.

(vii) Monensin as in § 558.355.

(viii) Narasin alone or with nicarbazin as in § 558.363.

(ix) Nicarbazin as in § 558.366.

(x) Salinomycin as in § 558.550.

(xi) Zoalene as in § 558.680.

§ 558.120 [Removed]

■ 11. Remove § 558.120.

■ 12. In § 558.128, revise paragraph (e)(7) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(7) Chlortetracycline may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Bacitracin methylene disalicylate as in § 558.76.

(iii) Clopidol as in § 558.175.

(iv) Decoquinate as in § 558.195.

(v) Hygromycin B as in § 558.274.

(vi) Laidlomycin as in § 558.305.

(vii) Lasalocid as in § 558.311.

(viii) Monensin as in § 558.355.

(ix) Robenidine as in § 558.515.

(x) Salinomycin as in § 558.550.

(xi) Tiamulin as in § 558.600.

§ 558.175 [Amended]

■ 13. In § 558.175, remove paragraphs (d)(3) and (8); and redesignate paragraphs (d)(4) through (7) as paragraphs (d)(3) through (6), respectively, and paragraphs (d)(9) through (11) as paragraphs (d)(7) through (9), respectively.

§ 558.195 [Amended]

■ 14. In § 558.195, remove paragraphs (e)(1)(iv) and (v) and redesignate paragraphs (e)(1)(vi) through (ix) as paragraphs (e)(1)(iv) through (vii), respectively.

§ 558.198 [Amended]

■ 15. In § 558.198, remove paragraphs (d)(1)(iii), (iv), and (vi) and redesignate paragraphs (d)(1)(v), (vii), and (viii) as paragraphs (d)(1)(iii), (iv), and (v), respectively.

■ 16. In § 558.248, remove paragraph (d)(3); and revise the section heading to read as follows:

§ 558.248 Erythromycin.

* * * * *

■ 17. In § 558.265, remove and reserve paragraphs (d)(1)(v) and (viii) and (d)(3)(ii) and revise the section heading to read as follows:

§ 558.265 Halofuginone.

* * * * *

■ 18. Revise § 558.274 to read as follows:

§ 558.274 Hygromycin B.

(a) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for Type A medicated articles or Type B medicated feeds as follow:

(1) No. 000986: 2.4 and 8 grams per pound (g/lb).

(2) Nos. 012286 and 051311: 2.4 g/lb.

(3) No. 017790: 0.6 g/lb.

(4) No. 054771: 0.6 and 1.6 g/lb.

(b) *Related tolerances.* See § 556.330 of this chapter.

(c) *Conditions of use.* It is used in feed as follows:

(1) *Chickens*—

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 8 to 12		Chickens: For control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).	Withdraw 3 days before slaughter	000986 012286 017790 054771
(ii) 8 to 12	Tylosin 4 to 50	Chickens: For control of infestations of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*); growth promotion and feed efficiency.	Withdraw 3 days before slaughter. Tylosin as tylosin phosphate as provided by No. 000986 in § 510.600 of this chapter.	000986

(2) *Swine*—

Hygromycin B in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 12		Swine: For control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*).	Withdraw 15 days before slaughter	000986 012286 017790 054771
(ii) 12	Tylosin 10 to 100	Swine: For control of infestations of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*); growth promotion and feed efficiency.	Feed continuously as follows: Animal weight (lbs.): Up to 40 . . . 20 to 100 [1] 41 to 100 . . . 20 to 40 [1] 101 to market weight . . . 10 to 20 [1] Withdraw 15 days before slaughter. Tylosin as tylosin phosphate as provided by No. 000986 in § 510.600 of this chapter.	000986

[1] Amount of Tylosin (g/t).

■ 19. In § 558.311:
■ a. In paragraph (e)(1)(ii), remove the entries for:
■ i.Roxarsone 45.4 (0.005 pct);
■ ii. Roxarsone 45.4 plus bambermycins 1 (0.00011 pct);
■ iii. Roxarsone 45.4 plus lincomycin 2.0;
■ iv. Roxarsone 45.4 plus bacitracin 10 to 25;
■ v. Roxarsone 45.4 plus bacitracin 10 or 30; and
■ vi. Roxarsone 45.4 plus bacitracin methylene disalicylate 50'';
■ b. In paragraph (e)(1)(xv), remove the entry for ''Roxarsone 22.7 to 45.4''; and
■ c. Revise paragraph (e)(5).

The revision reads as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(5) Lasalocid may also be used in combination with:

(i) Melengestrol acetate alone or in combination with tylosin as in § 558.342.

(ii) [Reserved]

■ 20. In § 558.325, revise paragraph (d)(3) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(d) * * *

(3) Lincomycin may also be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Clopidol as in § 558.175.

(iii) Decoquinate as in § 558.195.

(iv) Fenbendazole as in § 588.258.

(v) Halofuginone as in § 558.265.

(vi) Ivermectin as in § 558.300.

(vii) Lasalocid sodium as in § 558.311.

(viii) Monensin as in § 588.355.

(ix) Nicarbazin alone and with narasin as in § 558.366.

(x) Pyrantel as in § 558.485.

(xi) Robenidine as in § 558.515.

(xii) Salinomycin as in § 558.550.

(xiii) Zoalene as in § 558.680.

■ 21. In § 558.340, revise the section heading to read as follows:

§ 558.340 Maduramicin.

* * * * *

§ 558.355 [Amended]

■ 22. In § 558.355:
■ a. Remove and reserve paragraphs (f)(1)(ii), (vii), (x), (xi), (xii), (xv), (xvi), (xvii), (xviii), (xix), (xx), (xxiii), (xxvi), and (xxvii);
■ b. Remove and reserve paragraphs (f)(4)(vi) and (vii); and
■ c. Remove the second instance of a paragraph designated (f)(4)(iv) (following (f)(4)(vii).

§ 558.363 [Amended]

■ 23. In § 558.363:
■ a. Remove and reserve paragraphs (a)(2), (a)(5) and (a)(6);
■ b. Remove paragraphs (d)(1)(ii), (v), (vii), (viii), and (ix) and (d)(3)(iii) and (iv); and
■ c. Redesignate paragraphs (d)(1)(iii) and (iv) as paragraphs (d)(1)(ii) and (iii), paragraph (d)(1)(vi) as paragraph (d)(1)(iv), and paragraphs (d)(1)(x) and (xi) as paragraphs (d)(1)(v) and (vi).

§ 558.366 [Amended]

■ 24. In the table in § 558.366(d):
■ a. In the ''Nicarbazin in grams per ton'' column, following the entry for ''27 to 45'', remove the row entries for:
■ i. Narasin 27 to 45, bacitracin methylene disalicylate 50, and roxarsone 22.7 to 45.4; and
■ ii. Narasin 27 to 45 and roxarsone 22.7 to 45.4;
■ b. In the ''Nicarbazin in grams per ton'' column, following the entry for ''90.8 to 181.6 (0.01 to 0.02 pct)'', remove the row entry for ''Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4''; and
■ c. In the ''Nicarbazin in grams per ton'' column, following the entry for ''113.5 (0.0125 pct)'', remove the row entries for:
■ i. Roxarsone 22.7 (0.0025); and
■ ii. Roxarsone 22.7 (0.0025) plus lincomycin 2 (0.0004).''

§ 558.460 [Amended]

■ 25. In § 558.460, remove and reserve paragraph (d)(2).

■ 26. In § 558.515, in paragraph (d), remove the entries for ''Bacitracin (as bacitracin methylene disalicylate) 50 and roxarsone 22.7 to 45.4'', ''Bacitracin (as bacitracin methylene disalicylate) 100 to 200 and roxarsone 22.7 to 45.4'', and ''Roxarsone 22.5 to 45.4 (0.005 percent)''; and revise the section heading to read as follows:

§ 558.515 Robenidine.

* * * * *

§ 558.530 [Removed]

■ 27. Remove § 558.530.

§ 558.550 [Amended]

■ 28. In § 558.550, remove and reserve paragraphs (d)(1)(ii), (iv), (v), (viii), (ix), (xii), (xiv), (xv), (xvii), (xviii), (xix), and (xxiv) and (d)(3)(iv), (vi), and (vii).

§ 558.555 [Amended]

■ 29. In § 558.555, remove paragraphs (d)(3), (d)(4), and (d)(8); and redesignate paragraphs (d)(5), (d)(6), and (d)(7) as paragraphs (d)(3), (d)(4), and (d)(5), respectively.

§ 558.575 [Amended]

■ 30. In § 558.575, remove and reserve paragraph (d)(1)(ii).

■ 31. In § 558.680, revise paragraph (d) to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) *Conditions of use*—(1) *Chickens*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5	.....	Replacement chickens: For development of active immunity to coccidiosis.	Grower ration not to be fed to birds over 14 weeks of age; as follows:	054771

Growing conditions	Starter ration Grams per ton	Grower ration Grams per ton
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%)

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(ii) 36.3–113.5	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens: For development of active immunity to coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iii) 36.3–113.5	Bacitracin methylene disalicylate 50.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 36.3–113.5	Bacitracin methylene disalicylate 100 to 200.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 113.5	.....	Broiler chickens: For prevention and control of coccidiosis.	Feed continuously as sole ration	054771
(vi) 113.5	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) 113.5	Bacitracin methylene disalicylate 50.	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 113.5	Bacitracin methylene disalicylate 100 to 200.	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
(ix) 113.5	Bambermycins 1	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 14 weeks of age. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(x) 113.5	Lincomycin 2	Broiler chickens: As an aid in the prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. As lincomycin hydrochloride monohydrate provided by No. 054771 in § 510.600(c) of this chapter.	054771

(2) *Turkeys*—

Zoalene in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3	.....	Growing turkeys: For prevention and control of coccidiosis.	Feed continuously as sole ration. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771
(ii) 113.5 to 170.3	Bacitracin methylene disalicylate 4 to 50.	Growing turkeys: For prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 14 to 16 weeks of age. For turkeys grown for meat purposes only. Do not feed to laying birds.	054771

Dated: February 3, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–02617 Filed 2–26–14; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–370]

Schedules of Controlled Substances: Placement of Alfaxalone into Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration (DEA) places the substance 5α-pregnan-3α-ol-11,20-dione (alfaxalone), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle alfaxalone and substances containing alfaxalone.

DATES: *Effective Date:* March 31, 2014.

FOR FURTHER INFORMATION CONTACT: Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the ''Controlled Substances Act'' and the ''Controlled Substances Import and Export Act,'' respectively, and are collectively referred to as the ''Controlled Substances Act'' or the ''CSA'' for the purpose of this action. 21 U.S.C. 801–971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, ''add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed . . ..'' Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA. 28 CFR 0.104.

The CSA provides that scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS),[1] or (3) on the petition of any interested party. 21 U.S.C. 811(a). This action is based on a recommendation from the Assistant Secretary of the HHS and on an evaluation of all other relevant data by the DEA. This action imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule IV controlled substances on persons who handle or propose to handle alfaxalone.

Background

Alfaxalone (5α-pregnan-3α-ol-11,20-dione, previously spelled ''alphaxalone''), a substance with central nervous system (CNS) depressant properties, is a neurosteroid that is a derivative of 11-alpha-hydroxy-progesterone. On October 23, 2012, the Food and Drug Administration (FDA) published a final rule to approve a New Animal Drug Application (NADA, 141–342) for alfaxalone (Alfaxan®), as an intravenous injectable anesthetic, for the induction and maintenance of anesthesia and for induction of anesthesia followed by maintenance of anesthesia with an inhalant anesthetic, in cats and dogs (77 FR 64715). Alfaxalone primarily acts as an agonist at the gamma-aminobutyric acid (GABA) receptor-channel complex, with a mechanism of action at this site similar to that of barbiturates like phenobarbital (schedule IV) and methohexital (schedule IV), benzodiazepines such as diazepam (schedule IV) and midazolam (schedule IV), as well as the anesthetic agents

[1] As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1995. In addition, because the Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations, for purposes of this document, all subsequent references to ''Secretary'' have been replaced with ''Assistant Secretary.''