and in its place add ''048164, 054771, and 061623''.

§ 529.1940 [Amended]

■ 85. In paragraph (b) of § 529.1940, remove ''000009'' and in its place add ''054771''.

■ 86. Revise § 529.2464 to read as follows:

§ 529.2464 Ticarcillin.

(a) *Specifications.* Each vial contains ticarcillin disodium powder equivalent to 6 grams of ticarcillin for reconstitution with 25 milliliters of sterile water for injection or sterile physiological saline.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 6 grams daily by intrauterine infusion for 3 consecutive days during estrus.

(2) *Indications for use.* For the treatment of endometritis caused by beta-hemolytic streptococci.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 87. Revise § 529.2503 to read as follows:

§ 529.2503 Tricaine methanesulfonate.

(a) *Specifications.* The drug is ethyl-*m*-amino-benzoate methanesulfonate.

(b) *Sponsor.* See Nos. 050378 and 051212 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* It is used as follows:

(i) *Fish.* The drug is added to ambient water at a concentration of from 15 to 330 milligrams per liter depending upon the degree of anesthetization or sedation desired, the species and size of the fish, and the temperature and softness of the water. Preliminary tests of solutions must be made with small numbers of fish to determine the desired rates of sedation or anesthesia and the appropriate exposure times for the specific lots of fish under prevailing conditions.

(ii) *Amphibians and other aquatic coldblooded animals.* The drug is added to ambient water in concentrations of from 1:1000 to 1:20,000 depending upon species and stage of development.

(2) *Indications for use.* For the temporary immobilization of fish, amphibians, and other aquatic coldblooded animals (poikilotherms) as an aid in handling during manual spawning (fish stripping), weighing, measuring, marking, surgical operations, transport, photography, and research.

(3) *Limitations.* Do not use within 21 days of harvesting fish for food. Use in fish intended for food should be restricted to Ictaluridae, Salmonidae, Esocidae, and Percidae, and water temperature exceeding 10 °C (50 °F). In other fish and in coldblooded animals, the drug should be limited to hatchery or laboratory use.

Dated: January 27, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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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: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal 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.

DATES: Withdrawal of approval 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, November 22, 2013; 78 FR 69992, November 22, 2013; 78 FR 70566, November 26, 2013; 78 FR 70496, November 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).

NADA/ANADA	Ingredient new animal drugs
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).
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)/CLINICOX (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 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]

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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