Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2018–19–30 BAE Systems (Operations) Limited: Amendment 39–19431; Docket No. FAA–2018–0555; Product Identifier 2017–NM–152–AD.

(a) Effective Date

This AD is effective November 2, 2018.

(b) Affected ADs

None.

(c) Applicability

This AD applies to BAE Systems (Operations) Limited Model 4101 airplanes, certificated in any category, all serial numbers.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Reason

This AD was prompted by a report of an improperly installed spacer around the electrical pins in the cartridge connector for the fire bottle extinguisher cartridge. We are issuing this AD to detect and correct excessive or missing spacers, which could result in the fire extinguisher bottle not discharging when required, possibly resulting in damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection

Within 12 months after the effective date of this AD, do a general visual inspection of the inside of the cartridge electrical connector and the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of the BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(h) Inspections After Maintenance

As of the effective date of this AD, before further flight after each accomplishment of a maintenance task involving disconnection or (re-)connection of an electrical connector of a fire bottle extinguisher cartridge, do a general visual inspection of the inside of the cartridge electrical connector and the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(i) Corrective Actions

(1) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, more than one spacer is found inside the cartridge electrical connector: Before further flight, remove the excessive spacer(s) from the inside of the cartridge electrical connector in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(2) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, one or more spacers are found inside the airplane electrical connector: Before further flight, remove all spacers from the inside of the airplane electrical connector in accordance with the Accomplishment Instructions of BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(3) If, during any inspection as required by paragraph (g) or (h) of this AD, as applicable, no blue spacer is found inside the cartridge electrical connector body: Before further flight, replace the cartridge in accordance with the Accomplishment Instructions of the BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(j) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the International Section, send it to the attention of the person identified in paragraph (k)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov*. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or BAE Systems (Operations) Limited's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(k) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2017–0212, dated October 25, 2017, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0555.

(2) For more information about this AD, contact Todd Thompson, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th St., Des Moines, WA 98198; telephone and fax 206–231–3228.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) BAE Systems (Operations) Limited Service Bulletin J41–26–009, dated November 23, 2016.

(ii) Reserved.

(3) For service information identified in this AD, contact BAE Systems (Operations) Limited, Customer Information Department, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; telephone +44 1292 675207; fax +44 1292 675704; email *RApublications@baesystems.com*; internet *http://www.baesystems.com/Businesses/RegionalAircraft/index.htm.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Des Moines, Washington, on September 14, 2018.

John P. Piccola,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–20923 Filed 9–27–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 556, and 558

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2018. FDA is informing the public of the availability

of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect the withdrawal of approval of applications, changes of sponsorship of applications, and a change of a sponsor's name, and to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective September 28, 2018, except for amendatory instructions 7 to 21 CFR 520.580, 18 to 21 CFR 520.905d, 20 to 21 CFR 520.1182, 29 to 21 CFR 520.1840, 33 to 21 CFR 520.2380a, 37 to 21 CFR 522.1182, 51 to 21 CFR 524.900, 62 to 21 CFR 558.185, 68 to 21 CFR 558.365, and 70 to 21 CFR 558.485, which are effective October 9, 2018.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January, February, and March 2018, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2018

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 5, 2018.	141–449	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD AquaSol (fenbendazole oral suspension), Suspension Concentrate.	Chickens	Supplemental approval for the treatment and control of certain nematode worms in laying hens; and of a tolerance in chicken eggs.	FOI Summary; EA/FONSI [1].
January 16, 2018.	200–563	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	EPRIZERO (eprinomectin), Pour-On for Beef and Dairy Cattle.	Cattle	Original approval as a generic copy of NADA 141–079.	FOI Summary.
January 19, 2018.	141–494	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	CREDELIO (lotilaner), Chewable Tablet.	Dogs	Original approval for killing adult fleas, and for the treatment of flea infestations and the treatment and control of tick infestations in dogs.	FOI Summary.
January 29, 2018.	200–622	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.	Chlortetracycline and decoquinate, Type C medicated feeds.	Cattle	Original approval as a generic copy of NADA 141–185.	FOI Summary.
February 28, 2018.	141–482	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin) and ROBENZ (robenidine hydrochloride), Type C medicated feeds.	Chickens	Original approval for the control of necrotic enteritis and for the prevention of coccidiosis in broiler chickens.	FOI Summary.
February 28, 2018.	141–483	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin) and DECCOX (decoquinate), Type C medicated feeds.	Chickens	Original approval for the control of necrotic enteritis and for the prevention of coccidiosis in broiler chickens.	FOI Summary.
March 2, 2018	141–484	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin) and BIO–COX (salinomycin sodium), Type C medicated feeds.	Chickens	Original approval for the control of necrotic enteritis and for the prevention of coccidiosis in broiler chickens.	FOI Summary.
March 5, 2018	141–489	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin) and ZOAMIX (zoalene), Type C medicated feeds.	Chickens	Original approval for the control of necrotic enteritis and for the prevention and control of coccidiosis in broiler chickens.	FOI Summary.
March 8, 2018	141–492	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	CENTRAGARD (eprinomectin and praziquantel transdermal solution).	Cats	Original approval for the prevention of heartworm disease, and for the treatment and control of roundworms, hookworms, and tapeworms in cats and kittens.	FOI Summary.
March 26, 2018	141–491	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin) and COBAN (monensin), Type C medicated feeds.	Chickens	Original approval for the control of necrotic enteritis and as an aid in the prevention of coccidiosis in broiler chickens.	FOI Summary.

[1] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

II. Change of Sponsorship

Agri Laboratories Ltd., P.O. Box 3103, St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria:

File No.	Product name	21 CFR section
200–030	DI-METHOX (sulfadimethoxine) 12.5% Solution	520.2220a
200–031	DI-METHOX (sulfadimethoxine) Soluble Powder	520.2220a
200–037	LEGACY (gentamicin sulfate) Solution	529.1044a
200–038	DI-METHOX (sulfadimethoxine) Injection 40%	522.2220
200–049	TETRA-BAC 324 (tetracycline hydrochloride) Soluble Powder	520.2345d
200–061	FLU-NIX (flunixin meglumine) Injection	522.970
200–066	AGRIMYCIN-343 (oxytetracycline hydrochloride) Soluble Powder	520.1660d
200–128	AGRIMYCIN-200 (oxytetracycline dihydrate) Injection	522.1660a
200–185	GEN-GARD (gentamicin sulfate) Soluble Powder	520.1044c
200–225	PROHIBIT (levamisole hydrochloride) Soluble Drench Powder	520.1242a
200–271	Levamisole Phosphate Injection	522.1242
200–407	Lincomycin-Spectinomycin (lincomycin hydrochloride/spectinomycin dihydrochloride pentahydrate) Water Soluble Powder.	520.1265

Following this withdrawal of approval, Agri Laboratories Ltd. is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

Strategic Veterinary Pharmaceuticals, Inc., 100 NW Airport Rd., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816:

File No.	Product name	21 CFR section
011–531	DIZAN (dithiazanine iodide) Tablets	520.763a
011–674	DIZAN (dithiazanine iodide) Powder	520.763b
012–469	DIZAN (dithiazanine iodide) Suspension with Piperazine Citrate	520.763c
031–512	ATGARD (dichlorvos) Swine Wormer	558.205
033–803	TASK (dichlorvos) Dog Anthelmintic	520.600
035–918	EQUIGARD; VERDISOL (dichlorvos)	520.596
039–483	BIO-TAL (thiamylal sodium) Injection	522.2424
040–848	ATGARD C (dichlorvos) Swine Wormer	558.205
043–606	ATGARD V (dichlorvos) Swine Wormer	558.205
045–143	OXYJECT (oxytetracycline hydrochloride) Injection	522.1662a
047–278	BIO-MYCIN OXY-TET 50 (oxytetracycline hydrochloride) Injection	522.1662a
047–712	BIZOLIN–100; BIZOLIN–200 (phenylbutazone) Injection	522.1720
048–010	ANAPLEX (dichlorophene and toluene) Canine and Feline Wormer Caps	520.580
048–237	EQUIGEL (dichlorvos)	520.602
048–271	TASK (dichlorvos) Tablets	520.598
049–032	ATGARD C (dichlorvos) Premix 9.6%	558.205
065–461	ANACETIN (chloramphenicol) Tablets	520.390a
065–481	Calf Scour Boluses (chlortetracycline hydrochloride)	520.443
065–486	CTC Bisulfate (chlortetracycline bisulfate) Soluble Powder	520.441
065–491	MEDICHOL (chloramphenicol) Tablets	520.390a
092–837	NEMACIDE (diethylcarbamazine citrate) Oral Syrup	520.622b
093–516	BIZOLIN (phenylbutazone) Injection 20%	522.1720
097–452	OXYJECT 100 (oxytetracycline hydrochloride) Injection	522.1662a
098–569	MEDACIDE–SDM (sulfadimethoxine) Injection 10%	522.2220
099–618	BIZOLIN (phenylbutazone) 1–G Bolus	520.1720a
108–963	MEDAMYCIN (oxytetracycline hydrochloride) Injectable Solution	522.1662a
117–689	NEUROSYN (primidone) Tablets	520.1900
125–797	Nitrofurazone Dressing	524.1580a
126–236	Nitrofurazone Soluble Powder	524.1580b
126–676	D & T (dichlorophene and toluene) Worm Capsules	520.580
127–627	NEMACIDE; NEMACIDE–C (diethylcarbamazine citrate) Tablets	520.622a
128–069	NEMACIDE (diethylcarbamazine citrate) Chewable Tablets	520.622c
132–028	ANESTATAL (thiamylal sodium) Injectable Solution	522.2424
135–771	Methylprednisolene Tablets	520.1408
136–212	Methylprednisolone Acetate Injection	522.1410
137–310	Gentamicin Sulfate Injectable Solution	522.1044
138–869	Triamcinolone Acetonide Suspension	522.2483
140–442	Xylazine HCl Injection	522.2662
200–023	Gentamicin Sulfate Solution 100 mg/mL	522.1044
200–029	Ketamine Hydrochloride Injection	522.1222
200–165	SDM (sulfadimethoxine) Concentrated Solution 12.5%	520.2220a

The animal drug regulations are being amended to reflect these changes of sponsorship.

III. Withdrawals of Approval

Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137 has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
011–779	PURINA PIGEMIA 100 (colloidal ferric oxide)	522.1182
040–205	PURINA Horse Wormer Medicated (thiabendazole)	520.2380a
042–116	PURINA 6 DAY WORM–KILL Feed Premix (coumaphos)	558.185
043–215	PURINA GRUB–KILL Pour-on Cattle Insecticide (famphur)	524.900
046–700	STATYL (nequinate) Medicated Premix	558.365
091–260	PULVEX WORM CAPS (piperazine phosphate monohydrate)	520.1804
097–258	PURINA BAN–WORM for Pigs (pyrantel tartrate)	558.485
102–942	PULVEX Multipurpose Worm Caps (dichlorophene, toluene)	520.580
113–748	PURINA PIGEMIA Oral (iron dextran complex)	520.1182
135–941	CHECK–R–TON BM (pyrantel tartrate)	558.485
136–116	PURINA WORM–A–REST™ Litter Pack Premix (fenbendazole)	520.905d
140–869	PURINA SAF–T–BLOC BG Medicated Feed Block (poloxalene, 6.6%)	520.1840

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 011–779, 040–205, 042–116, 043–215, 046–700, 091–260, 097–258, 102–942, 113–748, 135–941, 136–116, and 140–869, and all supplements and amendments thereto, is withdrawn, effective October 9, 2018. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

IV. Technical Amendments

JBS United Animal Health II LLC, 322 S Main St., Sheridan, IN 46069 has informed FDA that it has changed its name to United-AH II LLC. Accordingly, we are amending § 510.600(c) to reflect this change.

We are also making technical amendments to update the scientific name of a pathogenic bacterium and to accurately list the concentrations of new animal drug ingredients in combination drug medicated feeds. These actions are being taken to improve the accuracy of the regulations.

V. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

21 CFR Part 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, 21 CFR parts 510, 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entry for ''JBS United Animal Health II LLC'', and alphabetically add an entry for ''United-AH II LLC''; and in the table in paragraph (c)(2), revise the entry for ''051233'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
United-AH II LLC, 322 S Main St., Sheridan, IN 46069	051233
* * * * * * *	
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051233	United-AH II LLC, 322 S Main St., Sheridan, IN 46069
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for part 520 continues to read as follows:

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

§ 520.390a [Amended]

■ 4. In § 520.390a, in paragraph (b)(1)(i), remove ''054628'' and in its place add ''069043''.

§ 520.441 [Amended]

■ 5. In § 520.441, in paragraph (b)(3), remove ''069254 and 076475'' and in its place add ''069043, 069254, and 076475''.

§ 520.443 [Amended]

■ 6. In § 520.443, in paragraph (b), remove ''054628'' and in its place add ''069043''.

§ 520.580 [Amended]

■ 7. In § 520.580, in paragraph (b)(1), remove ''051311''; and in paragraph (b)(2), remove ''000061 and 054771'', and in its place add ''000061, 054771, and 069043''.

§ 520.600 [Redesignated as § 520.596]

■ 8. Redesignate § 520.600 as § 520.596 and revise newly redesignated § 520.596 to read as follows:

§ 520.596 Dichlorvos powder.

(a) *Specifications*—(1) Each 2-ounce packet contains 2.27 grams (4 percent) dichlorvos.

(2) Each milligram of powder contains 2.27 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter for use of the product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section and the product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(c) *Related tolerances.* See § 556.180 of this chapter.

(d) *Conditions of use*—(1) *Swine* (adult gilts, sows, and boars)—(i) *Amount.* Add powder to the indicated amount of feed and administered shortly after mixing, as follows:

Weight of animal in pounds	Pounds of feed to be mixed with each 0.08 ounce of dichlorvos	Pounds of mixed feed to be administered to each pig as a single treatment	Number of pigs to be treated per 0.08 ounce of dichlorvos
20–30	4	0.33	12
31–40	5	0.56	9
41–60	6	1.00	6
61–80	5	1.00	5
81–100	4	1.00	4
	16	4.00	4

(ii) *Indications for use.* For the removal and control of sexually mature (adult), sexually immature and/or 4th stage larvae of the whipworm (*Trichuris suis*), nodular worms (*Oesophagostomum* spp.), large roundworm (*Ascaris suum*), and the mature thick stomach worm (*Ascarops strongylina*) occurring in the lumen of the gastrointestinal tract of pigs, boars, and open or bred gilts and sows.

(iii) *Limitations.* Do not use this product on animals either simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides, or chemicals. The preparation should be mixed thoroughly with the feed on a clean, impervious surface. Do not allow swine access to feed other than that containing the preparation until treatment is complete. Do not treat pigs with signs of scours until these signs subside or are alleviated by proper medication. Resume normal feeding schedule afterwards. Swine may be retreated in 4 to 5 weeks.

(2) *Horses*—(i) *Amount.* Administer in the grain portion of the ration at a dosage of 14.2 to 18.5 mg per pound of body weight as a single dose. Administered at one-half of the single

recommended dosage and repeated 8 to 12 hours later in the treatment of very aged, emaciated, or debilitated subjects or those reluctant to consume medicated feed. In suspected cases of severe ascarid infection sufficient to cause concern over mechanical blockage of the intestinal tract, the split dosage should be used.

(ii) *Indications for use.* For the removal and control of bots (*Gastrophilus intestinalis, G. nasalis*), large strongyles (*Strongylus vulgaris, S. equinus, S. edentatus*), small strongyles (of the genera *Cyathostomum, Cylicocercus, Cylicocyclus, Cylicodontophorus, Triodontophorus, Poteriostomum, Gyalocephalus*), pinworms (*Oxyuris equi*), and large roundworm (*Parascaris equorum*) in horses including ponies and mules. Not for use in foals (sucklings and young weanlings).

(iii) *Limitations.* Do not use in horses which are severely debilitated, suffering from diarrhea or severe constipation, infectious disease, toxemia, or colic. Do not administer in conjunction with or within 1 week of administration of muscle relaxant drugs, phenothiazine derived tranquilizers or central nervous system depressant drugs. Horses should not be subjected to insecticide treatment for 5 days prior to or after treating with the drug. Do not administer to horses afflicted with chronic alveolar emphysema (heaves) or related respiratory conditions. The product is a cholinesterase inhibitor and should not be used simultaneously or within a few days before or after treatment with or exposure to cholinesterase inhibiting drugs, pesticides or chemicals. Do not use in animals other than horses, ponies, and mules. Do not use in horses, ponies, and mules intended for food purposes. Do not allow fowl access to feed containing this preparation or to fecal excrement from treated animals.

■ 9. Add § 520.598 to read as follows:

§ 520.598 Dichlorvos tablets.

(a) *Specifications.* Each tablet contains 2, 5, 10, or 20 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs, puppies, cats, and kittens*—(1) *Amount.* Administer orally at 5 mg dichlorvos per pound of body weight.

(2) *Indications for use*—(i) *Dogs and puppies:* Removal and control of intestinal roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(ii) *Cats and kittens:* Removal and control of intestinal roundworms (*Toxocara cati* and *Toxascaris leonina*) and hookworms (*Ancylostoma tubaeforme* and *Uncinaria stenocephala*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 10. Add § 520.600 to read as follows:

§ 520.600 Dichlorvos capsules and pellets.

(a) *Specifications.* Each capsule contains 2.27 milligrams (mg) (4 percent) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer any combination of capsules and/or pellets so that the animal receives a single dose equaling 12 to 15 mg of dichlorvos per pound of body weight.

(2) *Indications for use.* For removal of *Toxocara canis* and *Toxascaris leonina* (roundworms), *Ancylostoma caninum* and *Uncinaria stenocephala* (hookworms), and *Trichuris vulpis* (whipworm) residing in the lumen of the gastrointestinal tract.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 11. Add § 520.602 to read as follows:

§ 520.602 Dichlorvos gel.

(a) *Specifications.* Each milligram (mg) of gel contains 2.27 milligrams (mg) dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 20 mg per kilogram of body weight for the removal of bots and ascarids. Repeat administration every 21 to 28 days for the control of bots and ascarids. For the control of bots only, the repeat dosage is 10 milligrams per kilogram of body weight every 21 to 28 days during bot fly season.

(2) *Indications for use.* For the removal and control of first, second, and third instar bots (*Gastrophilus intestinalis* and *G. nasalis*), sexually mature and sexually immature (4th stage) ascarids (*Parascaris equorum*) in horses and foals.

(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.

§ 520.622a [Amended]

■ 12. In § 520.622a, in paragraph (a)(6), remove ''054628'' and in its place add ''069043''.

§ 520.622b [Amended]

■ 13. In § 520.622b, in paragraph (c)(2), remove ''054628'' and in its place add ''069043''.

§ 520.622c [Amended]

■ 14. In § 520.622c, in paragraph (b)(6), remove ''054628'' and in its place add ''069043''.

§ 520.763a [Amended]

■ 15. In § 520.763a, in paragraph (b), remove ''054628'' and in its place add ''069043''.

§ 520.763b [Amended]

■ 16. In § 520.763b, in paragraph (b), remove ''000010'' and in its place add ''069043''.

§ 520.763c [Amended]

■ 17. In § 520.763c, in paragraph (b), remove ''054628'' and in its place add ''069043''.

■ 18. In § 520.905d, revise paragraphs (a) and (b) to read as follows:

§ 520.905d Fenbendazole powder.

(a) *Specifications.* Each 2-ounce packet contains 2.27 grams (4 percent) fenbendazole.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

* * * * *

§ 520.1044c [Amended]

■ 19. In § 520.1044c, in paragraph (b)(2), remove ''057561'' and in its place add ''016592''.

§ 520.1182 [Removed]

■ 20. Remove § 520.1182.

§ 520.1242a [Amended]

■ 21. In § 520.1242a, in paragraph (b)(3), remove ''057561'' and in its place add ''016592''.

§ 520.1263c [Amended]

■ 22. In § 520.1263c, in paragraph (b)(1), remove ''Nos. 016592 and 054771'' and in its place add ''No. 054771''; and in paragraph (b)(2), remove ''Nos. 054925, 061623, and 076475'' and in its place add ''Nos. 016592, 054925, 061623, and 076475''.

§ 520.1265 [Amended]

■ 23. In § 520.1265, in paragraph (b)(2), remove ''057561'' and in its place add ''016592''.

■ 24. Add § 520.1286 to read as follows:

§ 520.1286 Lotilaner.

(a) *Specifications.* Each chewable tablet contains 56.25, 112.5, 225, 450, or 900 milligrams (mg) lotilaner.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer orally once a month at the recommended minimum dosage of 9 mg/lb (20 mg/kg).

(2) *Indications for use.* Kills adult fleas, and for the treatment of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs and puppies 8 weeks of age or older and weighing 4.4 pounds or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.1408 [Amended]

■ 25. In § 520.1408, in paragraph (b)(1), remove ''054628'' and in its place add ''069043''.

§ 520.1660d [Amended]

■ 26. In § 520.1660d, in paragraph (b)(4), remove ''No. 057561'' and in its place add ''No. 016592''.

§ 20.1720a [Amended]

■ 27. In § 520.1720a, in paragraph (b)(2), remove ''Nos. 054628 and 069043'' and in its place add ''No. 069043''.

§ 520.1804 [Removed]

■ 28. Remove § 520.1804.

§ 520.1840 [Amended]

■ 29. In § 520.1840, remove paragraph (b)(2), redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3), and remove paragraph (d)(4).

§ 520.1900 [Amended]

■ 30. In § 520.1900, in paragraph (b)(1), remove ''054628'' and in its place add ''069043''.

§ 520.2220a [Amended]

■ 31. In § 520.2220a, in paragraph (b)(1), remove ''Nos. 016592, 054628, 054771, 054925, and 057561'' and in its place add ''Nos. 016592, 054771, 054925, and 069043''; and in paragraph (b)(2), remove ''Nos. 054771, 054925, 057561, 058829, 061623, and 066104'' and in its place add ''Nos. 016592, 054771, 054925, 058829, 061623, and 066104''.

§ 520.2345d [Amended]

■ 32. In § 520.2345d, in paragraph (b)(4), remove ''Nos. 054925, 057561, 061623, and 076475'' and in its place add ''Nos. 016592, 054925, 061623, and 076475''.

§ 520.2380a [Amended]

■ 33. In § 520.2380a, remove and reserve paragraphs (b)(1) and (d)(1)(i).

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 34. The authority citation for part 522 continues to read as follows:

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

§ 522.970 [Amended]

■ 35. In § 522.970, in paragraph (b)(1), remove ''Nos. 000061, 000859, 055529, 057561, and 061623'' and in its place add ''Nos. 000061, 000859, 016592, 055529, and 061623''.

§ 522.1044 [Amended]

■ 36. In § 522.1044, in paragraph (b)(3), remove ''054628'' and in its place add ''069043''.

§ 522.1182 [Amended]

■ 37. In § 522.1182, in paragraph (b)(4), remove ''Nos. 051311 and 054771'' and in its place add ''No. 054771''.

§ 522.1222 [Amended]

■ 38. In § 522.1222, in paragraph (b), remove ''Nos. 000859, 026637, 054628, 054771, 059399, and 063286'' and in its place add ''Nos. 000859, 026637, 054771, 059399, 063286, and 069043''.

§ 522.1242 [Amended]

■ 39. In § 522.1242, in paragraph (b), remove ''057561'' and in its place add ''016592''.

§ 522.1410 [Amended]

■ 40. In § 522.1410, in paragraph (b), remove ''054628 and 054771'' and in its place add ''054771 and 069043''.

§ 522.1660a [Amended]

■ 41. In § 522.1660a, in paragraph (b), remove ''057561,''.

§ 522.1662a [Amended]

■ 42. In § 522.1662a, in paragraphs (a)(2), (b)(2), (g)(2), and (h)(2), remove ''054628'' and in its place add ''069043''.

§ 522.1720 [Amended]

■ 43. In § 522.1720, in paragraph (b)(3), remove ''054628 and 058005'' and in its place add ''058005 and 069043''.

§ 522.2220 [Amended]

■ 44. In § 522.2220, in paragraph (b)(1), remove ''054628'' and in its place add ''069043''; and in paragraph (b)(3), remove ''Nos. 016592, 057561, and 061623'' and in its place add ''Nos. 016592 and 061623''.

§ 522.2424 [Amended]

■ 45. In § 522.2424, in paragraph (b), remove ''054628 and 054771'' and in its place add ''054771 and 069043''.

§ 522.2483 [Amended]

■ 46. In § 522.2483, in paragraph (b), remove ''054628'' and in its place add ''069043''.

§ 522.2662 [Amended]

■ 47. In § 522.2662, in paragraph (b)(1), remove ''054628'' and in its place add ''069043''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 48. The authority citation for part 524 continues to read as follows:

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

■ 49. In § 524.814, revise paragraph (b) to read as follows:

§ 524.814 Eprinomectin.

* * * * *

(b) *Sponsors.* See Nos. 050604 and 055529 in § 510.600(c) of this chapter.

* * * * *

■ 50. Add § 524.815 to read as follows:

§ 524.815 Eprinomectin and praziquantel.

(a) *Specifications.* Each milliliter (mL) of solution contains 4 milligrams (mg) eprinomectin and 83 mg praziquantel.

(b) *Sponsor.* See No. 050604 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Using the 0.3 mL and 0.9 mL unit applicators, administer a minimum dose of 0.23 mg eprinomectin per pound body weight and 4.55 mg praziquantel per pound body weight by topical application on the dorsal midline between the base of the skull and the shoulder blades.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis,* and for the treatment and control of roundworms (adult and fourth stage larval *Toxocara cati*), hookworms (adult and fourth stage larval *Ancylostoma tubaeforme;* adult *Ancylostoma braziliense*), and tapeworms (adult *Dipylidium caninum* and *Echinococcus multilocularis*), in cats and kittens 7 weeks of age and older and 1.8 lbs or greater.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 524.900 [Amended]

■ 51. In § 524.900, in paragraph (b), remove ''Nos. 000061 and 051311'' and in its place add ''No. 000061''.

§ 524.1580a [Amended]

■ 52. In § 524.1580a, in paragraph (b)(1), remove ''Nos. 054628, 054925, 058005, 059051, and 061623'' and in its place add ''Nos. 054925, 058005, 059051, 061623, and 069043''.

§ 524.1580b [Amended]

■ 53. In § 524.1580b, in paragraph (b), remove ''054628 and 059051'' and in its place add ''059051 and 069043''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 54. The authority citation for part 529 continues to read as follows:

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

§ 529.1044a [Amended]

■ 55. In § 529.1044a, in paragraph (b), remove ''Nos. 000061, 000859, 054628, 054771, 057561, 058005, and 061623'' and in its place add ''Nos. 000061, 000859, 016592, 054628, 054771, 058005, and 061623''.

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

■ 56. The authority citation for part 556 continues to read as follows:

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

■ 57. In § 556.275, add paragraph (b)(3)(ii) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(3) * * *

(ii) *Eggs.* The tolerance for fenbendazole sulfone (the marker residue) is 1.8 ppm.

* * * * *

§ 556.440 [Removed]

■ 58. Remove § 556.440.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 59. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 558.4 [Amended]

■ 60. In § 558.4, in paragraph (d), in the ''Category I'' table, remove the row entry for ''Nequinate''.

§ 558.128 [Amended]

■ 61. In § 558.128, in paragraphs (e)(4)(xi) and (xiii), in the ''Indications for use'' column, remove ''*P. multocida*'' and in its place add ''*P. multocida* organisms''.

■ 62. In § 558.185, revise paragraph (b), remove paragraph (e)(1), and redesignate paragraphs (e)(2) and (3) as paragraphs (e)(1) and (2).

The revision reads as follows:

§ 558.185 Coumaphos.

* * * * *

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

* * * * *

§ 558.195 [Amended]

■ 63. In § 558.195, remove and reserve paragraph (e)(2)(v).

■ 64. In § 558.205, revise paragraph (a); redesignate paragraphs (b) through (d) as paragraphs (c) through (e); and add new paragraph (b).

The revision and addtion read as follows:

§ 558.205 Dichlorvos.

(a) *Specifications.* Type A medicated articles containing 3.1 or 9.6 percent dichlorvos.

(b) *Sponsor.* See No. 069043 in § 510.600(c) of this chapter.

* * * * *

■ 65. In § 558.311, revise paragraph (e)(5) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

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

(i) Chlortetracycline as in § 558.128.

(ii) Melengestrol as in § 558.342.

(iii) Oxytetracycline as in § 558.450.

(iv) Tylosin alone or in combination with melengestrol acetate as in § 558.625.

(v) Virginiamycin as in § 558.635.

■ 66. In § 558.325, redesignate paragraph (e)(1)(ii) as paragraph (e)(1)(v); add reserved paragraphs (e)(1)(ii), (iii), and (vi); and add paragraphs (e)(1)(iv), (vii), (viii), (ix), and (x) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(1) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*	*	*
(ii) [Reserved]				
(iii) [Reserved]				
(iv) 2	Decoquinate, 2.72	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed as the sole ration. Do not use in feeds containing bentonite. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Decoquinate as provided by No. 054771 in § 510.600 of this chapter.	054771
*	*	*	*	*	*	*
(vi) [Reserved]				
(vii) 2	Monensin, 90 to 110	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed as the sole ration. Must be thoroughly mixed in feeds before use. Do not feed undiluted. Not for use in laying hens, breeding chickens, or turkeys. Do not allow horses, or other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Monensin as provided by No. 058198 in § 510.600 of this chapter.	054771

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(viii) 2	Robenidine hydrochloride, 30.	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and as an aid in the prevention of coccidiosis caused by *Eimeria mivati, E. brunetti, E. tenella, E. acervulina, E. maxima,* and *E. necatrix*.	Feed as the sole ration. Do not use in feeds containing bentonite. Do not feed to laying hens producing eggs for human consumption. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Withdraw 5 days prior to slaughter. Type C feed containing robenidine hydrochloride must be fed within 50 days from the date of manufacture. Robenidine hydrochloride as provided by No. 054771 in § 510.600 of this chapter.	054771
(ix) 2	Salinomycin sodium, 40 to 60.	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin, and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E maxima, E. brunetti,* and *E. mivati*.	Feed as the sole ration to broiler chickens. Do not feed to laying hens producing eggs for human consumption. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Salinomycin sodium as provided by No. 054771 in § 510.600 of this chapter.	054771
(x) 2	Zoalene, 113.5	Broiler chickens: For the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to lincomycin; and for the prevention and control of coccidiosis.	Feed as the sole ration from the time chicks are placed in floor pens until slaughtered for meat. Not for use in laying hens, breeding chickens, or turkeys. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Zoalene as provided by No. 054771 in § 510.600 of this chapter.	054771

* * * * *

■ 67. In § 558.342, in paragraph (e)(1), revise the table headings, add paragraphs (e)(1)(iii) and (iv), and remove paragraphs (e)(1)(v) through (xi); and in paragraph (e)(2), redesignate paragraphs (e)(2)(i) through (iii) as paragraphs (e)(2)(ii) through (iv) and add new paragraph (e)(2)(i).

The revisions and additions read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(iii) 0.25 to 0.5	Lasalocid, 10 to 30	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 30 g of lasalocid per ton to provide 0.25 to 0.5 mg melengestrol acetate and 100 to 360 milligrams of lasalocid per head/day. See § 558.311(d) of this chapter. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771 058198
(iv) 0.25 to 0.5	Monensin, 10 to 40	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Add at the rate of 0.5 to 2.0 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1.0 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d) of this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	054771 058198

(2) * * *

(i) Oxytetracycline as in § 558.450.

* * * * *

§ 558.365 [Removed]

■ 68. Remove § 558.365.

§ 558.450 [Amended]

■ 69. In § 558.450, in paragraph (e)(5)(iv) entries 1 and 2, remove ''*A. liquefaciens*'' and in its place add ''*A. hydrophila*''.

■ 70. Revise § 558.485 to read as follows:

§ 558.485 Pyrantel.

(a) *Specifications.* Type A medicated articles containing 48 or 80 grams per pound pyrantel tartrate.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (e) of this section.

(1) No. 066104: 48 and 80 grams per pound for use as in paragraph (e)(1) of this section.

(2) Nos. 017135 and 054771: 48 grams per pound for use as in paragraph (e)(2) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Special considerations*—(1) See § 500.25 of this chapter. Consult a veterinarian before using in severely debilitated animals.

(2) Do not mix in Type B or Type C medicated feeds containing bentonite.

(e) *Conditions of use*—(1) *Swine*—

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
(i) 96	Swine: As an aid in the prevention of migration and establishment of large roundworm (*Ascaris suum*) infections; aid in the prevention of establishment of nodular worm (*Oesophagostomum*) infections.	Feed continuously as the sole ration in a Type C feed. Withdraw 24 hours prior to slaughter.	066104
(ii) 96	Swine: For the removal and control of large roundworm (*Ascaris suum*) infections.	Feed for 3 days as the sole ration in a Type C feed. Withdraw 24 hours prior to slaughter.	066104
(iii) 800	Swine: For the removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.	Feed as the sole ration for a single therapeutic treatment in Type C feed at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb, and 5 lb of feed per head for animals 200 lb or over. Withdraw 24 hours prior to slaughter.	066104

(2) *Horses*—

Pyrantel grams/ton	Indications for use	Limitations	Sponsor
To provide 1.2 mg/lb body weight.	Prevention of *Strongylus vulgaris* larval infections; control of adult large strongyles (*S. vulgaris,* and *S. edentatus*), adult and 4th stage larvae small strongyles (*Cyathostomum* spp., *Cylicocyclus* spp., *Cylicostephanus* spp., *Cylicodontophorus* spp., *Poteriostomum* spp., and *Triodontophorus* spp.), adult and 4th stage larvae pinworms (*Oxyuris equi*), and adult and 4th stage larvae ascarids (*Parascaris equorum*).	Feed continuously. Administer either as a top-dress (not to exceed 20,000 g/ton) or mixed in the horse's daily grain ration (not to exceed 1,200 g/ton) during the time that the animal is at risk of exposure to internal parasites. Not for use in horses intended for food. Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.	017135 054771

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

(i) Carbadox as in § 558.115.

(ii) Lincomycin as in § 558.325.

(iii) Tylosin as in § 558.625.

■ 71. In § 558.625, revise paragraphs (e)(2)(ii) and (iii) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 8 to 10	Lasalocid, 100 to 1440; plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Feed to heifers at the rate of 0.5 to 2.0 pound(s) per head per day (specify one level) to provide 0.25 to 0.5 mg melengestrol acetate per head per day (specify one level), 100 to 360 mg lasalocid per head per day (specify one level), and 90 mg tylosin per head per day. This Type C product may be top dressed onto or mixed into a complete feed prior to feeding. Tylosin as provided by Nos. 016592 and 058198; lasalocid as provided by No. 054771; melengestrol as provided by Nos. 054771 and 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.342(d) in this chapter.	016592 054771 058198
(iii) 8 to 10	Melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes;* and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration. Each pound contains 0.125 to 1.0 mg melengestrol acetate and 45 to 180 mg of tylosin. Feed to heifers at a rate of 0.5 to 2.0 pounds per head per day to provide 0.25 to 0.5 mg melengestrol acetate and 60 to 90 mg tylosin per head per day. Prior to feeding, this Type C product must be top-dressed onto a complete feed or mixed into the amount of complete feed consumed by an animal per day. Tylosin provided by Nos. 016592 and 058198; melengestrol provided by Nos. 054771 and 058198 in § 510.600(c) of this chapter. See § 558.342(d) in this chapter.	016592 054771 058198
*	*	*	*	*

Dated: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 524, and 558

[Docket No. FDA–2018–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 12 new animal drug applications (NADAs) at the sponsor's request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective October 9, 2018.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137, has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
011–779 ...	PURINA PIGEMIA 100 (colloidal ferric oxide).	522.1182
040–205 ...	PURINA Horse Wormer Medicated (thiabendazole).	520.2380a
042–116 ...	PURINA 6 DAY WORM-KILL Feed Premix (coumaphos).	558.185
043–215 ...	PURINA GRUB-KILL Pour-on Cattle Insecticide (famphur).	524.900
046–700 ...	STATYL Medicated Premix (nequinate).	558.365
091–260 ...	PULVEX WORM CAPS (piperazine phosphate monohydrate).	520.1804
097–258 ...	PURINA BAN-WORM for Pigs (pyrantel tartrate).	558.485
102–942 ...	PULVEX Multipurpose Worm Caps (dichlorophene, toluene).	520.580
113–748 ...	PURINA PIGEMIA Oral (iron dextran complex).	520.1182
135–941 ...	CHECK-R-TON BM (pyrantel tartrate).	558.485
136–116 ...	PURINA WORM-A-REST™ Litter Pack Premix (fenbendazole).	520.905d
140–869 ...	PURINA SAF-T-BLOC BG Medicated Feed Block (poloxalene, 6.6%).	520.1840

Therefore, under authority delegated to the Commissioner of Food and Drugs, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 011–779, 040–205, 042–116, 043–215, 046–700, 091–260, 097–258, 102–942, 113–748, 135–941, 136–116, and 140–869, and all supplements and amendments thereto, is hereby withdrawn, effective October 9, 2018.

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: September 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–21147 Filed 9–27–18; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1308, 1312

[Docket No. DEA–486]

Schedules of Controlled Substances: Placement in Schedule V of Certain FDA-Approved Drugs Containing Cannabidiol; Corresponding Change to Permit Requirements

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: With the issuance of this final order, the Acting Administrator of the Drug Enforcement Administration places certain drug products that have been approved by the Food and Drug Administration (FDA) and which contain cannabidiol (CBD) in schedule V of the Controlled Substances Act (CSA). Specifically, this order places FDA-approved drugs that contain CBD derived from cannabis and no more than 0.1 percent tetrahydrocannabinols in schedule V. This action is required to satisfy the responsibility of the Acting Administrator under the CSA to place a drug in the schedule he deems most appropriate to carry out United States obligations under the Single Convention on Narcotic Drugs, 1961. Also consistent therewith, DEA is adding such drugs to the list of substances that may only be imported or exported pursuant to a permit.

DATES: Effective September 28, 2018.

FOR FURTHER INFORMATION CONTACT: Kathy L. Federico, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

The United States is a party to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and other international conventions designed to establish effective control over international and domestic traffic in controlled substances. 21 U.S.C. 801(7). The Single Convention entered into force for the United States on June 24, 1967, after the Senate gave its advice and consent to the United States' accession. *See* Single Convention, 18 U.S.T. 1407. The enactment and enforcement of the Controlled Substances Act (CSA) are the primary means by which the United States carries out its obligations under the Single Convention.[1] Various provisions of the CSA directly reference the Single Convention. One such provision is 21 U.S.C. 811(d)(1), which relates to scheduling of controlled substances.

As stated in subsection 811(d)(1), if control of a substance is required ''by United States obligations under international treaties, conventions, or protocols in effect on October 27, 1970, the Attorney General shall issue an order controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by [subsections 811(a) or 812(b)] and without regard to the procedures prescribed by [subsections 811(a) and (b)].'' This provision is consistent with the Supremacy Clause of the U.S. Constitution (art. VI, sec. 2), which provides that all treaties made under the authority of the United States ''shall be the supreme Law of the Land.'' In accordance with this constitutional

[1] *See* S. Rep. No. 91–613, at 4 (1969) (''The United States has international commitments to help control the worldwide drug traffic. To honor those commitments, principally those established by the Single Convention on Narcotic Drugs of 1961, is clearly a Federal responsibility.''); *Control of Papaver Bracteatum,* 1 Op. O.L.C. 93, 95 (1977) (''[A] number of the provisions of [the CSA] reflect Congress' intent to comply with the obligations imposed by the Single Convention.'').