that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866,

2. Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

3. Will not affect intrastate aviation in Alaska, and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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):

2019–05–03 Leonardo S.p.A.: Amendment 39–19585; Docket No. FAA–2019–0092; Product Identifier 2019–SW–022–AD.

(a) Applicability

This AD applies to the following helicopters, certificated in any category:

(1) Model AB139 and AW139 helicopters with a tail rotor (T/R) duplex bearing part number (P/N) 3G6430V00153, and serial number (S/N) 16181 through 16225, S/N 16237 through 16259, S/N 17101 through 17110, S/N 17182 through 17194, S/N 17204 through 17217, and S/N 17251 through S/N 17260; and

(2) Model AW169 and AW189 helicopters with a T/R duplex bearing P/N 4F6430V00551, and S/N 16165 through 16169, S/N 16171, and S/N 17101 through 17121.

(b) Unsafe Condition

This AD defines the unsafe condition as failure of a T/R duplex bearing ball. This condition could result in premature degradation of the T/R duplex bearing, loss of T/R control, and subsequent loss of control of the helicopter.

(c) Effective Date

This AD becomes effective March 28, 2019.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

(1) Within 30 hours time-in-service, remove from service any T/R duplex bearing with a P/N and S/N listed in paragraphs (a)(1) or (a)(2) of this AD.

(2) After the effective date of this AD, do not install a T/R duplex bearing with a P/N and S/N listed in paragraphs (a)(1) or (a)(2) of this AD on any helicopter.

(f) Special Flight Permits

Special flight permits are prohibited.

(g) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Section, Rotorcraft Standards Branch, FAA, may approve AMOCs for this AD. Send your proposal to: David Hatfield, Aviation Safety Engineer, Safety Management Section, Rotorcraft Standards Branch, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(h) Additional Information

(1) Leonardo Helicopters Service Bulletin (SB) Alert No. 139–571, Leonardo Helicopters SB Alert No. 169–134, and Leonardo Helicopters SB Alert No. 189–221, each dated February 1, 2019, which are not incorporated by reference, contain additional information about the subject of this AD. For service information identified in this AD, contact Leonardo S.p.A. Helicopters, Matteo Ragazzi, Head of Airworthiness, Viale G.Agusta 520, 21017 C.Costa di Samarate (Va) Italy; telephone +39–0331–711756; fax +39–0331–229046; or at *http://www.leonardocompany.com/-/bulletins.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2019–0022, dated February 1, 2019, and corrected February 4, 2019. You may view the EASA AD on the internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2019–0092.

(i) Subject

Joint Aircraft Service Component (JASC) Code: 6400, Tail Rotor System.

Issued in Fort Worth, Texas, on March 6, 2019.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2019–04529 Filed 3–12–19; 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, 526, 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

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 July, August, and September 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 make technical amendments to improve the readability of the regulations.

DATES: This rule is effective March 13, 2019, except for amendatory instruction 25 to 21 CFR 520.2041, which is effective March 25, 2019.

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 July, August, and September 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 JULY, AUGUST, AND SEPTEMBER 2018

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
July 2, 2018	200–624	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186.	REVERTIDINE (atipamezole hydrochloride) Sterile Injectable Solution.	Dogs	Original approval as a generic copy of NADA 141–033.	FOI Summary.
July 6, 2018	200–495	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	ENROFLOX 100 (enrofloxacin) Injectable Solution.	Swine	Supplemental approval of additional indications and routes of administration.	FOI Summary.
July 11, 2018	138–952	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	MAXIBAN 72 (narasin and nicarbazin) Type A medicated article.	Chickens	Supplemental approval of a revised tissue residue tolerance for nicarbazin and withdrawal period for narasin and nicarbazin Type C medicated feeds.	FOI Summary EA/FONSI.[1]
July 13, 2018	200–484	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET (tylosin phosphate) Type A medicated articles.	Swine and cattle.	Supplemental approval of a 40 g/lb strength Type A medicated article.	FOI Summary.
July 13, 2018	141–406	Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	NEXGARD (afoxolaner) Chewable Tablets.	Dogs	Supplemental approval for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.	FOI Summary.
July 30, 2018	200–608	Piedmont Animal Health, 204 Muirs Chapel Rd., Suite 200, Greensboro, NC 27410.	BAYTRIL (enrofloxacin) Soft Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 140–441.	FOI Summary.
August 3, 2018 ..	141–461	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	NOCITA (bupivacaine liposome injectable suspension).	Cats	Supplemental approval to provide for use as a peripheral nerve block to provide regional postoperative analgesia following onychectomy in cats.	FOI Summary.
August 8, 2018 ..	141–439	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	INTEPRITY (avilamycin) Type A medicated article.	Chickens	Supplemental approval of a revised age restriction caution statement from 10 days to 18 days for use of avilamycin Type C medicated broiler feeds.	FOI Summary EA/FONSI.[1]
August 9, 2018 ..	200–630	Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009.	COCCIAID (amprolium) 9.6% Oral Solution.	Chickens and turkeys.	Original approval as a generic copy of NADA 013–149.	FOI Summary.
August 10, 2018	141–488	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	Lincomycin and lasalocid Type C medicated feeds.	Chickens	Original approval for use of LINCOMIX (lincomycin) and AVATEC (lasalocid) Type A medicated articles in the manufacture of Type C medicated broiler chicken feeds 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*.	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

Piedmont Animal Health, 204 Muirs Chapel Rd., Suite 200, Greensboro, NC 27410 has informed FDA that it has transferred ownership of, and all rights and interest in, newly approved ANADA 200–608 for BAYTRIL (enrofloxacin) Soft Chewable Tablets to Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201. Following this change of sponsorship, Piedmont Animal Health is no longer the sponsor of an approved application. Accordingly, it will not be added to the

list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

Cronus Pharma LLC, 2 Tower Center Blvd., Suite 1101, East Brunswick, NJ 08816 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Cronus Pharma Specialities India Private Ltd., Sy No: 99/1, M/s GMR Hyderabad Aviation SEZ L, Mamidipalli Village, Shamshabad Mandal, Ranga, Hyderabad, Telangana 501218, India:

File No.	Product name
011–531	DIZAN (dithiazanine iodide) Tablets.
011–674	DIZAN (dithiazanine iodide) Powder.
012–469	DIZAN (dithiazanine iodide) Suspension with Piperazine.
031–512	ATGARD (dichlorvos) Swine Wormer.
033–803	TASK (dichlorvos) Dog Anthelmintic.
035–918	EQUIGARD (dichlorvos).
039–483	BIO-TAL (thiamylal sodium).
040–848	ATGARD C (dichlorvos) Swine Wormer.
043–606	ATGARD V (dichlorvos) Swine Wormer.
045–143	OXIJECT (oxytetracycline hydrochloride).
047–278	BIO-MYCIN (oxytetracycline hydrochloride).
047–712	BIZOLIN-100 (phenylbutazone).
048–010	ANAPLEX (dichlorophene and toluene) Capsules.
048–237	EQUIGEL (dichlorvos).
048–271	TASK (dichlorvos) Tablets.
049–032	ATGARD C (dichlorvos) Premix.
055–002	TEVCOCIN (chloramphenicol).
065–461	ANACETIN (chloramphenicol) Tablets.
065–481	Chlortetracycline Calf Scour Boluses.
065–486	CTC Bisulfate (chlortetracycline bisulfate) Soluble Powder.
065–491	MEDICHOL (chloramphenicol) Tablets.
092–837	NEMACIDE (diethylcarbamazine citrate) Oral Syrup.
093–516	BIZOLIN (phenylbutazone) Injection 20%.
094–170	Phenylbutazone Tablets, U.S.P. 100 mg.
097–452	OXYJECT 100 (oxytetracycline hydrochloride).
098–569	MEDACIDE-SDM (sulfadimethoxine) Injection 10%.
099–618	BIZOLIN (phenylbutazone) 1-gram.
108–963	MEDAMYCIN (oxytetracycline hydrochloride).
117–689	NEUROSYN (primidone) Tablets.
123–815	Dexamethasone Sodium Phosphate Injection.
125–797	Nitrofurazone Dressing.
126–236	Nitrofurazone Soluble Powder.
126–676	D & T (dichlorophene and toluene) Worm Capsules.
127–627	NEMACIDE-C (diethylcarbamazine citrate).
128–069	NEMACIDE (diethylcarbamazine citrate) Chewable Tablets.
132–028	ANESTATAL (thiamylal sodium).
135–771	Methylprednisolene Tablets.
136–212	Methylprednisolone Acetate Injection.
137–310	Gentamicin Sulfate Injectable Solution.
138–869	Triamcinolone Acetonide Suspension.
140–442	Xylazine Hydrochloride Injection.
141–245	TRIBUTAME (chloroquine phosphate, embutramid, lidocaine) Euthanasia Solution.
200–023	Gentamicin Sulfate Solution 100 mg/mL.
200–029	Ketamine Hydrochloride Injection.
200–165	SDM Sulfadimethoxine Concentrated Solution 12.5%.
200–178	Amikacin Sulfate Injection.
200–193	Clindamycin Hydrochloride Oral Liquid.
200–248	Pyrantel Pamoate Suspension.
200–265	Praziquantel Tablets.
200–287	GBC (gentamicin sulfate, betamethasone valerate, clotrimazole) Ointment.
200–297	Ivermectin Chewable Tablets.
200–298	Clindamycin Hydrochloride Capsules.
200–365	ROBINUL (glycopyrrolate) Injection.
200–382	Furosemide Syrup 1%.

Following this change of sponsorship, Cronus Pharma LLC 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). As a new sponsor of approved applications, Cronus Pharma Specialities India Private Ltd. will be added to § 510.600(c); however, as the drug labeler code was not changed, no further amendments are necessary.

Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland:

File No.	Product name	21 CFR section
010–092	GALLIMYCIN-100P (erythromycin thiocyanate) Type A Medicated Article	558.248.
010–346	COMBUTHAL (pentobarbital sodium and thiopental sodium) Powder	522.2444b.
012–123	GALLIMYCIN-100 (erythromycin) Injectable	522.820.
035–157	GALLIMYCIN PFC (erythromycin phosphate) Powder	520.823.
035–455	GALLIMYCIN-36 (erythromycin) Dry Cow Intramammary Infusion	526.820.
035–456	GALLIMYCIN-36 (erythromycin) Sterile Intramammary Infusion	526.820.
038–661	SPECTOGARD (spectinomycin) Water Soluble Powder	520.2123b.
044–756	BUTATRON (phenylbutazone) Tablets	520.1720a.
046–780	PHEN-BUTA (phenylbutazone) Vet Injection	522.1720.
049–187	PHEN-BUTA (phenylbutazone) Vet Tablets	520.1720a.
055–059	VICETRON (chloramphenicol) Tablets	520.390a.
065–383	UNIBIOTIC (penicillin G procaine) Intramammary Infusion	526.1696a.
065–505	PRO-PEN-G (penicillin G procaine) Injectable Suspension	522.1696b.
065–506	COMBI-PEN-48 (penicillin G benzathine and penicillin G procaine) Injectable Suspension	522.1696a.
092–150	PURINA (pyrantel tartrate) Horse & Colt Wormer Pellets	520.2046.
093–515	SPECTAM (spectinomycin) Tablets	520.2123a.
095–218	DEXIUM (dexamethasone) Tablets	520.540b.
096–671	PHEN-BUTA-Vet (phenylbutazone) Injection	522.1720.
096–672	PHEN-BUTA (phenylbutazone) Vet Tablets	520.1720a.
098–288	PREDNIS-A-Vet (prednisolone sodium phosphate) Injection	522.1883.
099–169	Oxytocin Injection	522.1680.
099–604	DEX-A-VET (dexamethasone) Injection	522.540.
099–605	DEX-A-VET (dexamethasone) Injection	522.540.
099–606	DEXAMETH-A-Vet (dexamethasone) Injection	522.540.
099–607	DEXAMETH-A-Vet (dexamethasone) Injection	522.540.
101–690	ERYTHRO-100 (erythromycin) Injection	522.820.
107–506	CARBAM (diethylcarbamazine citrate) Tablets	520.622a.
109–305	Oxytocin Injection	522.1680.
118–032	PALATABS (diethylcarbamazine citrate) Tablets	520.622a.
118–550	FUROS-A-Vet (furosemide)	522.1010.
118–979	BUTATRON (phenylbutazone) Gel	520.1720d.
119–141	TRANQUAZINE (promazine hydrochloride) Injection	522.1962.
120–615	SUSTAIN III (sulfamethazine) Bolus	520.2260b.
122–447	FURA-SEPTIN (Nitrofurazone) Soluble Dressing	524.1580a.
124–241	PVL Oxytocin Injection	522.1680.
126–504	Nitrofurazone Ointment	524.1580a.
130–136	Oxytocin Injection	522.1680.
138–405	Pyrilamine Maleate Injection	522.2063.
140–582	Oxytetracycline Hydrochloride Injection	522.1662a.
140–583	ACTH (adrenocorticotropic hormone) Gel	522.480.
141–420	TILDREN (tiludronate disodium) Powder for Injection	522.2473.
200–050	NEOMED (neomycin sulfate) Soluble Powder	520.1484.
200–069	FERTELIN (gonadorelin diacetate tetrahydrate)	522.1077.
200–103	PENAQUA Sol-G (penicillin G potassium, USP) Soluble Powder	520.1696b.
200–115	GENTAMEX 100 (gentamicicn sulfate)	529.1044a.
200–117	OXYSHOT-LA (oxytetracycline) Injectable Solution	522.1660a.
200–144	TETROXY HCA-280 (oxytetracycline hydrochloride) Soluble Powder	520.1660d.
200–146	TETROXY 25 (oxytetracycline hydrochloride) Soluble Powder	520.1660d.
200–176	PRAZITECH (praziquantel) Injection	522.1870.
200–247	TETROXY 343 (oxytetracycline hydrochloride) Soluble Powder	520.1660d.
200–253	PROSTAMATE (dinoprost tromethamine) Injectable Solution	522.690.
200–312	DEXIUM (dexamethasone) Injection	522.540.
200–313	LEVAMED (levamisole hydrochloride) Soluble Powder	520.1242a.
200–317	DEXIUM-SP (dexamethasone sodium phosphate) Injection	522.540.
200–318	BIMECTIN (ivermectin) Pour-On	524.1193.
200–326	BIMECTIN (ivermectin) Paste	520.1192.
200–328	Oxytocin Injection	522.1680.
200–350	EXODUS (pyrantel pamoate) Paste	520.2044.
200–364	SPECTOGARD SCOUR-CHEK (spectinomycin dihydrochloride pentahydrate) Oral Solution	520.2123c.
200–368	LINCOMED 100 (lincomycin hydrochloride) Injectable Solution	522.1260.
200–374	TETRAMED 324 HCA (tetracycline hydrochloride) Soluble Powder	520.2345d.
200–376	SULFAMED-G (sulfadimethoxine) Soluble Powder	520.2220a.
200–377	LINXMED-SP (lincomycin hydrochloride) Soluble Powder	520.1263c.
200–380	SPECLINX-50 (lincomycin hydrochloride monohydrate and spectinomycin dihydrochloride pentahydrate) Soluble Powder.	520.1265.
200–386	LEVAMED (levamisole hydrochloride) Soluble Drench Powder	520.1242a.
200–387	FLUNAZINE (flunixin meglumine) Injection	522.970.
200–391	Griseofulvin Powder	520.1100.
200–434	SMZ-Med 454 (sodium sulfamethazine) Soluble Powder	520.2261b.
200–447	BIMECTIN (ivermectin) Injection for Cattle and Swine	522.1192.
200–455	BILOVET (tylosin tartrate) Soluble Powder	520.2640.
200–460	TETROXY (oxytetracycline hydrochloride) Aquatic	529.1660.
200–464	AMPROMED (amprolium) For Cattle	520.100.

File No.	Product name	21 CFR section
200–468	GENTAMED-P (gentamicin sulfate) for Poultry Injection	522.1044.
200–481	OVAMED (altrenogest) Solution	520.48.
200–482	AMPROMED (amprolium) for Calves	520.100.
200–488	AMPROMED P (amprolium) for Poultry	520.100.
200–489	FLUNAZINE-S (flunixin meglumine) Injection	522.970.
200–494	GENTAMED (gentamicin sulfate) Soluble Powder	520.1044c.
200–496	AMPROMED P (amprolium) for Poultry	520.100.
200–501	Praziquantel Injection	522.1870.
200–508	BILOVET (tylosin) Injectable Solution	522.2640.
200–523	SULFAMED (sulfadimethoxine) Injection	522.2220.
200–529	XYLAMED (xylazine) Injection	522.2662.
200–538	CLINDAMED (clindamycin) Oral Drops	520.447.
200–581	FLUNAZINE (flunixin meglumine) Paste	520.970.

Following this change of sponsorship, Cross Vetpharm Group 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)). As a new sponsor of approved applications, Bimeda Animal Health Ltd. will be added to § 510.600(c) and the regulations amended to reflect this action. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Withdrawals of Approval

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 140–939 for use of RUMENSIN (monensin) and TYLAN (tylosin phosphate) Type A medicated articles in the manufacture of combination drug Type C medicated cattle feeds because the product is no longer manufactured or marketed.

Also, Sergeant's Pet Care Products, Inc., 10077 S 134th St., Omaha, NE 68138 has requested that FDA withdraw approval of ANADA 200–600 for WORMX (pyrantel pamoate) Flavored Tablets because the product is no longer manufactured or marketed.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 140–939 and ANADA 200–600, and all supplements and amendments thereto, is withdrawn, effective March 25, 2019. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

IV. Technical Amendments

In addition, we are reformatting the regulations to present the approved conditions of use of halofuginone, monensin, and salinomycin in tabular format in the respective named sections of 21 CFR part 558. This action is being taken to improve the readability 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) because it is a ''rule of particular applicability'' under 5 U.S.C. 804(3)(A). 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, 526, 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, 526, 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 entries for ''Cronus Pharma LLC'' and ''Cross Vetpharm Group Ltd.'' and alphabetically add entries for ''Bimeda Animal Health Ltd.'' and ''Cronus Pharma Specialities India Private Ltd.''; and in the table in paragraph (c)(2), numerically add an entry for ''061133'', remove the entry for ''061623'', and revise the entry for ''069043''.

The additions and revisions 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
* * * * * * *	
Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland	061133

Firm name and address	Drug labeler code
* * * * * * *	
Cronus Pharma Specialities India Private Ltd., Sy No: 99/1, M/s GMR Hyderabad Aviation SEZ L, Mamidipalli Village, Shamshabad Mandal, Ranga, Hyderabad, Telangana, 501218, India	069043
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
061133	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.
* * * * * * *	
069043	Cronus Pharma Specialities India Private Ltd., Sy No: 99/1, M/s GMR Hyderabad Aviation SEZ L, Mamidipalli Village, Shamshabad Mandal, Ranga, Hyderabad, Telangana, 501218, India.
* * * * * * *	

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.

■ 4. In § 520.43, revise paragraph (c)(2) to read as follows:

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(2) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*); for the treatment and control of black-legged tick (*Ixodes scapularis*), American dog tick (*Dermacentor variabilis*), lone star tick (*Amblyomma americanum*), and brown dog tick (*Rhipicephalus sanguineus*) infestations in dogs and puppies 8 weeks of age and older, weighing 4 pounds of body weight or greater, for 1 month; and for the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

§ 520.48 [Amended]

■ 5. In § 520.48, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.100 [Amended]

■ 6. In § 520.100, in paragraph (b)(1), remove ''No. 016592'' and in its place add ''Nos. 016592 and 061133''; and in paragraph (b)(2), remove ''No. 066104'' and in its place add ''Nos. 051072 and 066104''.

§ 520.390a [Amended]

■ 7. In § 520.390a, in paragraph (b)(2)(i), remove ''061623'' and in its place add ''061133''.

§ 520.447 [Amended]

■ 8. In § 520.447, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.540b [Amended]

■ 9. In § 520.540b, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.622a [Amended]

■ 10. In § 520.622a, in paragraph (a)(3), remove ''061623'' and in its place add ''061133''.

■ 11. In § 520.812, revise paragraphs (a) and (b)(1) and (2) and add paragraph (b)(3) to read as follows:

§ 520.812 Enrofloxacin.

(a) *Specifications*—(1) Each tablet contains:

(i) 2.7, 68.0, or 136.0 milligrams (mg) enrofloxacin; or

(ii) 22.7, 68.0, 136.0, or 272 mg enrofloxacin.

(2) Each soft chewable tablet contains 22.7, 68.0, or 136.0 mg enrofloxacin.

(b) * * *

(1) Nos. 000859 and 026637 for use of product described in paragraph (a)(1)(i) of this section.

(2) No. 058198 for use of product described in paragraph (a)(1)(ii) of this section.

(3) No. 000859 for use of product described in paragraph (a)(2) of this section.

* * * * *

§ 520.823 [Amended]

■ 12. In § 520.823, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.970 [Amended]

■ 13. In § 520.970, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1044c [Amended]

■ 14. In § 520.1044c, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1100 [Amended]

■ 15. In § 520.1100, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1192 [Amended]

■ 16. In § 520.1192, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1242a [Amended]

■ 17. In § 520.1242a, in paragraph (b)(4), remove ''059130'' and in its place add ''061133''.

§ 520.1263c [Amended]

■ 18. In § 520.1263c, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1265 [Amended]

■ 19. In § 520.1265, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1484 [Amended]

■ 20. In § 520.1484, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.1660d [Amended]

■ 21. In § 520.1660d, in paragraphs (b)(5), (b)(7), (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), (d)(1)(ii)(C)(*3*), and (d)(1)(iii)(C), remove ''061623'' and in its place add ''061133''.

§ 520.1696b [Amended]

■ 22. In § 520.1696b, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.1720a [Amended]

■ 23. In § 520.1720a, in paragraph (b)(3), remove ''061623'' and in its place add ''061133''.

§ 520.1720d [Amended]

■ 24. In § 520.1720d, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.2041 [Amended]

■ 25. Effective March 25, 2019, in § 520.2041, in paragraph (b), remove ''066916, 017135,'' and add in its place ''017135''.

§ 520.2044 [Amended]

■ 26. In § 520.2044, in paragraph (b)(3), remove ''061623'' and in its place add ''061133''.

§ 520.2046 [Amended]

■ 27. In § 520.2046, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.2123a [Amended]

■ 28. In § 520.2123a, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.2123b [Amended]

■ 29. In § 520.2123b, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.2123c [Amended]

■ 30. In § 520.2123c, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.2220a [Amended]

■ 31. In § 520.2220a, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 520.2260b [Amended]

■ 32. In § 520.2260b, in paragraphs (c)(1) and (e)(1), remove ''061623'' and in its place add ''061133''.

§ 520.2261b [Amended]

■ 33. In § 520.2261b, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 520.2345d [Amended]

■ 34. In § 520.2345d, in paragraph (b)(4), remove ''061623'' and in its place add ''061133''; and in paragraphs (d)(1)(iii) and (d)(2)(iii), remove ''059130, and 061623'' and in its place add ''and 061133''.

§ 520.2640 [Amended]

■ 35. In § 520.2640, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.147 [Amended]

■ 37. In § 522.147, in paragraph (b), remove ''No. 052483'' and in its place add ''Nos. 015914 and 052483''.

■ 38. In § 522.224, revise paragraph (c) to read as follows:

§ 522.224 Bupivacaine.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 5.3 mg/kg (0.4 mL/kg) by infiltration injection into the tissue layers at the time of incisional closure.

(ii) *Indications for use.* For single-dose infiltration into the surgical site to provide local postoperative analgesia for cranial cruciate ligament surgery.

(2) *Cats*—(i) *Amount.* Administer 5.3 mg/kg per forelimb (0.4 mL/kg per forelimb), for a total dose of 10.6 mg/kg/cat, as a 4-point nerve block prior to onychectomy.

(ii) *Indications for use.* For use as a peripheral nerve block to provide regional postoperative analgesia following onychectomy.

§ 522.480 [Amended]

■ 39. In § 522.480, in paragraph (b)(1), remove ''061623'' and in its place add ''061133''.

§ 522.540 [Amended]

■ 40. In § 522.540, in paragraphs (a)(2)(i), (b)(2), and (c)(2), remove ''061623'' and in its place add ''061133''.

§ 522.690 [Amended]

■ 41. In § 522.690, in paragraph (b)(3), remove ''061623'' and in its place add ''061133''.

■ 42. In § 522.812, revise paragraph (b)(1); remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2); remove paragraph (e)(3)(i)(B) and redesignate paragraph (e)(3)(i)(C) as (e)(3)(i)(B); and revise paragraphs (e)(3)(i)(A) and newly designated (e)(3)(i)(B).

The revisions read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 000859 and 055529 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section, and use of product described in paragraph (a)(2) of this section as in paragraphs (e)(2) and (3) of this section.

* * * * *

(e) * * *

(3) * * *

(i) * * *

(A) Administer 7.5 mg/kg of body weight once, by intramuscular or subcutaneous injection behind the ear, for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica, and Mycoplasma hyopneumoniae.*

(B) Administer 7.5 mg/kg of body weight once, by intramuscular or subcutaneous injection behind the ear, for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

* * * * *

§ 522.820 [Amended]

■ 43. In § 522.820, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.970 [Amended]

■ 44. In § 522.970, in paragraph (b)(1), remove ''061623'' and in its place add ''061133''.

§ 522.1010 [Amended]

■ 45. In § 522.1010, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.1044 [Amended]

■ 46. In § 522.1044, in paragraph (b)(4), remove ''061623'' and in its place add ''061133''.

§ 522.1077 [Amended]

■ 47. In § 522.1077, in paragraph (b)(3), remove ''061623'' and in its place add ''061133''.

§ 522.1192 [Amended]

■ 48. In § 522.1192, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.1260 [Amended]

■ 49. In § 522.1260, in paragraph (b)(4), remove ''061623'' and in its place add ''061133''.

§ 522.1660a [Amended]

■ 50. In § 522.1660a, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.1662a [Amended]

■ 51. In § 522.1662a, in paragraph (k)(2), remove ''061623'' and in its place add ''061133''.

§ 522.1680 [Amended]

■ 52. In § 522.1680, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.1696a [Amended]

■ 53. In § 522.1696a, in paragraphs (b)(1), (b)(2), and (d)(2)(iii), remove ''061623'' and in its place add ''061133''; and in paragraphs (d)(1)(ii) and (d)(2)(ii), remove ''*Conditions of use*'' and in its place add ''*Indications for use*''.

§ 522.1696b [Amended]

■ 54. In § 522.1696b, in paragraphs (b)(2), (d)(2)(i)(A), and (d)(2)(iii)(A), remove ''061623'' and in its place add ''061133''.

§ 522.1720 [Amended]

■ 55. In § 522.1720, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.1870 [Amended]

■ 56. In § 522.1870, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.1883 [Amended]

■ 57. In § 522.1883, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.1962 [Amended]

■ 58. In § 522.1962, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.2063 [Amended]

■ 59. In § 522.2063, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.2220 [Amended]

■ 60. In § 522.2220, in paragraph (b)(3), remove ''061623'' and in its place add ''061133''.

§ 522.2444b [Amended]

■ 61. In § 522.2444b, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.2473 [Amended]

■ 62. In § 522.2473, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 522.2640 [Amended]

■ 63. In § 522.2640, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

§ 522.2662 [Amended]

■ 64. In § 522.2662, in paragraph (b)(2), remove ''061623'' and in its place add ''061133''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1193 [Amended]

■ 66. In § 524.1193, in paragraph (b)(1), remove ''061623'' and in its place add ''061133''.

§ 524.1580a [Amended]

■ 67. In § 524.1580a, in paragraph (b)(1), remove ''061623'' and in its place add ''061133''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 68. The authority citation for part 526 continues to read as follows:

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

§ 526.820 [Amended]

■ 69. In § 526.820, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 526.1696a [Amended]

■ 70. In § 526.1696a, in paragraph (c), remove ''061623'' and in its place add ''061133''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1044a [Amended]

■ 72. In § 529.1044a, in paragraph (b), remove ''061623'' and in its place add ''061133''.

§ 529.1660 [Amended]

■ 73. In § 529.1660, in paragraphs (b)(1) and (2), remove ''061623'' and in its place add ''061133''.

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

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

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

■ 75. In § 556.445, add paragraph (a) and revise paragraph (b) to read as follows:

§ 556.445 Nicarbazin.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of nicarbazin (4,4′-dinitrocarbanilide and 2-hydroxy-4,6-dimethylpyrimidine) is 200 micrograms per kilogram of body weight per day.

(b) *Tolerance.* The tolerance for 4,4′-dinitrocarbanilide (marker residue) is:

(1) *Chickens—Liver (target tissue):* 52 ppm.

(2) [Reserved]

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 77. In § 558.4, in paragraph (d), in the ''Category I'' table, revise the entry for ''Narasin'', alphabetically add an entry for ''Nicarbazin (granular)'' followed immediately by an indented entry for ''Narasin''; and in the ''Category II'' table, remove the entry for ''Narasin'' and revise the entry for ''Nicarbazin (powder)''.

The revisions and addition read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY I

Drug	Assay limits percent [1] Type A	Type B maximum (200x)	Assay limits percent [1] Type B/C [2]
* * * *	*	* *	*
Narasin	90–110	9.0 g/lb (1.98%)	85–115/75–125.
Nicarbazin (granular)	90–110	9.0 g/lb (1.98%)	85–115/75–125.
Narasin	90–110	9.0 g/lb (1.98%)	85–115/75–125.
* * * *	*	* *	*

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

CATEGORY II

Drug	Assay limits percent [1] Type A	Type B maximum (100x)	Assay limits percent [1] Type B/C [2]
* * * *	*	* *	*
Nicarbazin (powder)	90–110	9.08 g/lb (2.00%)	85–115/75–125.
* * * *	*	* *	*

[1] Percent of labeled amount.
[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

* * * * *

§ 558.68 [Amended]

■ 78. In § 558.68, in paragraph (e)(1)(i), in the ''Limitations'' column, remove ''10 days of age'' and in its place add ''18 days of age''.

§ 558.128 [Amended]

■ 79. In § 558.128, in paragraph (e)(4)(iv), in the row for ''1.'', in the ''Limitations'' column, remove ''sponsor No. 069254'' and in its place add ''sponsor Nos. 054771 and 069254''.

§ 558.248 [Amended]

■ 80. In § 558.248, in paragraph (b), remove ''061623'' and in its place add ''061133''.

■ 81. In § 558.265, revise paragraphs (b) and (d) to read as follows:

§ 558.265 Halofuginone.

* * * * *

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

* * * * *

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

(1) *Chickens*—

Halofuginone in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 2.72		Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed continuously as sole ration. Do not feed to layers. Withdraw 4 days before slaughter.	016592
(ii) 2.72	Bacitracin methylenedisalicylate, 10 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima;* for improved feed efficiency.	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days before slaughter.	016592
(iii) 2.72	Bambermycins, 1 to 2.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E, acervulina, E. brunetti, E. mivati,* and *E. maxima;* for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days before slaughter.	016592
(iv) 2.72		Replacement broiler breeder chickens and replacement cage laying chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. mivati/E. mitis,* and *E. brunetti*.	Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Do not feed to laying chickens or water fowl. Withdraw 4 days before slaughter.	016592

(2) *Turkeys*—

Halofuginone in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.36 to 2.72 ...	.....	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis*.	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to layers or water fowl.	016592
(ii) 1.36 to 2.72 ..	Bacitracin methylenedisalicylate, 10 to 50.	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain.	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl.	016592
(iii) 1.36 to 2.72	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain.	Feed continuously as sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or waterfowl.	016592

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

(i) Lincomycin as in § 558.325.

(ii) [Reserved]

■ 82. In § 558.311, redesignate paragraphs (e)(5)(ii) through (v) as paragraphs (e)(5)(iii) and (vi), and add new paragraph (e)(5)(ii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(5) * * *

(ii) Lincomycin as in § 558.325.

* * * * *

■ 83. In § 558.325, add paragraph (e)(1)(vi) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(1) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	*	*
(vi) 2	Lasalocid, 68 to 113	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. Type C feed must be used within 4 weeks of manufacture. 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. Lasalocid as provided by No. 054771 in § 510.600 of this chapter.	054771
*	*	*	*	*

* * * * *

■ 84. In § 558.355, revise paragraph (b), add paragraph (c), and revise paragraph (f) to read as follows:

§ 558.355 Monensin.

* * * * *

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

(c) *Related tolerances.* See § 556.420 of this chapter.

* * * * *

(f) *Conditions of use.* It is used as follows:

(1) *Chickens*—

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 90 to 110 ..	.....	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed continuously as the sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens.	058198
(ii) 90 to 110 ..	.....	Replacement chickens intended for use as cage layers: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens.	058198

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iii) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for improved feed efficiency.	Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(iv) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50.	Replacement chickens intended for use as cage layers: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(v) 90 to 110	Bacitracin methylenedisalicylate, 5 to 25.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. Bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	058198
(vi) 90 to 110	Bacitracin methylenedisalicylate, 50.	Broiler and replacement chickens intended for use as cage layers: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for improved feed efficiency, 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. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
(vii) 90 to 110	Bacitracin zinc, 4 to 50.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. Bacitracin zinc provided by No. 054771 in § 510.600(c) of this chapter.	054771
(viii) 90 to 110	Bacitracin zinc, 10 ...	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. Bacitracin zinc provided by No. 054771 in § 510.600(c) of this chapter.	058198
(ix) 90 to 110	Bacitracin zinc, 10 to 30.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for improved feed efficiency.	Feed continuously as sole ration. In the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Do not feed to laying chickens. Bacitracin zinc provided by No. 054771 in § 510.600(c) of this chapter.	058198
(x) 90 to 110	Bambermycins, 1 to 2.	Broiler chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Bambermycins provided by No. 016592 in § 510.600(c) of this chapter.	016592, 058198

(2) *Turkeys*—

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 54 to 90	.....	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis*.	For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.	058198
(ii) 54 to 90	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency.	For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iii) 54 to 90 ...	Bacitracin methylenedisalicylate, 200.	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate.	For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	058198
(iv) 54 to 90 ...	Bambermycins, 1 to 2.	Growing turkeys: For the prevention of coccidiosis in turkeys caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for improved feed efficiency.	For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198
(v) 54 to 90 ...	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain and improved feed efficiency.	For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.	058198

(3) *Cattle*—

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency.	Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day).	058198
(ii) 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	Feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day.	058198

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(iii) 10 to 200	Calves excluding veal calves: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	Feed at a rate of 0.14 to 1.0 milligram monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 200 milligrams per head per day.	058198
(iv) 11 to 22	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).	Feed continuously to dry and lactating dairy cows in a total mixed ration (''complete feed''). See special labeling considerations in paragraph (d) of this section.	058198
(v) 11 to 400	Dairy cows: For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake).	Feed continuously to dry and lactating dairy cows in a component feeding system (including top dress). The Type C medicated feed must be fed in a minimum of 1 lb of feed to provide 185 to 660 mg/head/day monensin to lactating cows or 115 to 410 mg/head/day monensin to dry cows. See special labeling considerations in paragraph (d) of this section.	058198
(vi) 15 to 400	Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	For increased rate of weight gain, feed at a rate of 50 to 200 milligrams monensin per head per day in not less than 1 pound of feed or, after the 5th day, feed at a rate of 400 milligrams per head per day every other day in not less than 2 pounds of feed. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending on severity of challenge, up to 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per day in not less than 1 pound of feed.	058198
(vii) 25 to 400	For improved feed efficiency, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	Feed to mature reproducing beef cows. Feed as supplemental feed, either hand-fed in a minimum of 1 pound of feed or mixed in a total ration. For improved feed efficiency, feed continuously at a rate of 50 to 200 milligrams monensin per head per day. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligram per pound of body weight per day, depending upon severity of challenge, up to a maximum of 200 milligrams per head per day. During first 5 days of feeding, cattle should receive no more than 100 milligrams per head per day.	058198

(4) *Free-choice cattle feeds*—

Monensin amount	Indications for use	Limitations	Sponsor
(i) 150 milligrams per pound of protein-mineral block (0.033%).	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis caused by *E. bovis* and *E. zuernii* in pasture cattle which may require supplemental feed.	Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.	058198
(ii) 175 milligrams per pound of protein-mineral block (0.038%).	Pasture cattle (slaughter, stocker, and feeder): For increased rate of weight gain.	Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.	017800
(iii) 400 milligrams per pound of protein-mineral block (0.088%).	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain.	Provide 80 to 200 milligrams of monensin (0.2 to 0.5 pounds of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.	067949

Monensin amount	Indications for use	Limitations	Sponsor
(iv) 400 milligrams per pound of block (0.088%).	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain.	Provide 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.	051267
(v) In free-choice Type C medicated feeds to provide 50 to 200 mg per head per day.	Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated supplement before using the monensin medicated supplement. The product's effectiveness in cull cows and bulls has not been established. See paragraph (d) of this section for other required label warnings.	058198
(vi) 1,620 grams per ton of mineral granules as specified in paragraph (f)(4)(vi)(A) of this section.	Growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers): For increased rate of weight gain, and for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*.	Feed at a rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or feed- and/or water-deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using the monensin mineral supplement. The product's effectiveness in cull cows and bulls has not been established.	058198

(A) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–082
Sodium chloride (salt)	24.37	6–04–152
Dried cane molasses	20.0	4–04–695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6–02–632
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix [1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1] Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(B) [Reserved]

(5) *Bobwhite quail*—

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 73	Growing bobwhite quail: For the prevention of coccidiosis caused by *Eimeria dispersa* and *E. lettyae*.	Feed continuously in complete feed at a rate of 50 to 480 milligrams of monensin per head per day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 grams per ton (360 milligrams per head per day).	058198
(ii) [Reserved]			

(6) *Goats*—

Monensin in grams/ton	Indications for use	Limitations	Sponsor
(i) 5 to 40	For the prevention of coccidiosis caused by *Eimeria crandallis, E. christenseni,* and *E. ninakohlyakimovae*.	Feed only to goats being fed in confinement. Do not feed to lactating goats. See paragraph (d)(13) of this section for provisions for monensin liquid Type C goat feeds.	058198
(ii) [Reserved]	.....	.....	.....

(7) Monensin may also be used in combination with:
(i) Avilamycin as in § 558.68.
(ii) Chlortetracycline as in § 558.128.
(iii) Decoquinate as in § 558.195.
(iv) Lincomycin as in § 558.325.
(v) Melengestrol acetate as in § 558.342.
(vi) Oxytetracycline as in § 558.450.
(vii) Ractopamine alone or in combination as in § 558.500.
(viii) Tilmicosin as in § 558.618.
(ix) Tylosin as in § 558.625.
(x) Virginiamycin as in § 558.635.
(xi) Zilpaterol alone or in combination as in § 558.665.

■ 85. In § 558.364, revise paragraph (d)(1)(i) to read as follows:

§ 558.364 Narasin and nicarbazin.

* * * * *

(d) * * *

(1) * * *

Narasin and nicarbazin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 27 to 45 of each drug.	.....	Broiler chickens: For prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. The two drugs can be combined only at a 1:1 ratio for the 27 to 45 grams per ton range. Only granular nicarbazin as provided by No. 058198 in § 510.600(c) of this chapter may be used in the combination.	058198
*	*	*	*	*	*	*

* * * * *

■ 86. In § 558.550, revise paragraph (b), add paragraph (c), revise paragraph (d), and add paragraph (e) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(b) *Sponsor.* See No. 016592 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.592 of this chapter.

(d) *Special considerations.* Not approved for use with pellet binders.

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

(1) *Chickens*—

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 40 to 60	.....	Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as sole ration. Do not feed to laying hens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses.	016592
(ii) 40 to 60	Bacitracin methylenedisalicylate, 4 to 50.	Broiler, roaster, and replacement (breeder and layer) chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. May be fatal if fed to adult turkeys or horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	016592 054771
(iii) 40 to 60	Bacitracin methylenedisalicylate, 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* 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. Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.	054771

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 40 to 60	Bacitracin methylenedisalicylate, 100 to 200.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* 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 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 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.	054771
(v) 40 to 60	Bacitracin zinc, 10 to 50.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain.	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	016592 054771
(vi) 40 to 60	Bambermycins, 1 to 3.	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin and bambermycins as provided by No. 016592 in § 510.600(c) in this chapter.	016592

(2) *Game birds*—

Salinomycin in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50	.....	Quail: For the prevention of coccidiosis caused by *E. dispersa* and *E. lettyae*.	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses.	.....
(ii) [Reserved] ..	.....	.....	.....	.....

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

(i) Chlortetracycline as in § 558.128.

(ii) Lincomycin as in § 558.325.

(iii) Oxytetracycline as in § 558.450.

(iv) Virginiamycin as in § 558.635.

■ 87. In § 558.625, revise paragraphs (b)(1) through (4) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(1) No. 016592: Type A medicated articles containing 40 or 100 grams per pound (g/lb).

(2) No. 054771: Type A medicated article containing 40 g/lb.

(3) No. 058198: Type A medicated articles containing 10, 40, or 100 g/lb.

(4) No. 066104: Type A medicated articles containing 20 or 40 g/lb.

* * * * *

Dated: March 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2018–N–0002]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and an abbreviated new animal drug application (ANADA) at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective March 25, 2019.

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: Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 140–939 for use of RUMENSIN (monensin) and TYLAN (tylosin phosphate) Type A medicated articles in the manufacture of combination drug Type C medicated cattle feeds because the product is no longer manufactured or marketed.