4164-01-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 [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], except for amendatory instruction 25 to 21 CFR 520.2041, which is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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
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 [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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
* * * * * * *	
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 026637for 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 [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], 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	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days before slaughter.	016592

		E. maxima; for improved feed efficiency.		
(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	Bacitracin	Growing turkeys: For	Feed continuously as	016592

2.72	methylenedisalicylate, 10 to 50	the prevention of coccidiosis caused by *Eimeria adenoeides, E. meleagrimitis,* and *E. gallopavonis,* and for increased rate of weight gain	sole ration. Withdraw 7 days before slaughter. Do not feed to laying chickens or water fowl.	
(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
(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
(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

(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
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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

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(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
(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,*	Feed continuously as sole ration. Not approved for use with pellet binders. Do not	016592 054771

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
		E. necatrix, E. acervulina, E. maxima, E. brunetti, and *E. mivati,* and for increased rate of weight gain	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.	
(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.

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Dated: March 5, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

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