



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 528, and 558

[Docket No. FDA-2025-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsor Address

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 April, May, and June 2025. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Cathie Marshall, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-5693, cathie.marshall@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2025, as listed in table 1. Documentation of environmental review required under the National Environmental Policy Act, summaries of the basis of approval under the Freedom of Information Act (FOIA summaries), and marketing exclusivity and patent information are available at Animal Drugs @ FDA: <https://animaldrugsatfda.fda.gov/adafda/views/#!/search>.

Table 1.--Original And Supplemental Applications Approved During April, May, and June 2025

Date of approval	Application No.	Sponsor (drug labeler code ¹)	Product name	Effect of the action	21 CFR sections
March 24, 2025 ²	200-811	Bimeda Animal Health Ltd. (061133)	MOXICLOPRID for Cats (imidacloprid and moxidectin) Topical Solution	Original approval as a generic copy of NADA 141-254	524.1146
March 24, 2025 ³	200-810	Hikma Pharmaceuticals USA, Inc. (086194)	Enrofloxacin Flavored Tablets (enrofloxacin flavored tablets)	Original approval as a generic copy of NADA 140-441	520.812
April 3, 2025	200-791	Cronus Pharmaceuticals Specialities India Private Ltd. (069043)	FLUNINE-S (flunixin meglumine injection) Injectable Solution	Original approval as a generic copy of NADA 101-479	522.970
April 7, 2025	141-586	Phibro Animal Health Corp. (066104)	V-MAX (virginiamycin), RUMENSIN (monensin), and EXPERIOR (lubabegron) Type A medicated articles to be used in the manufacture of Type B and Type C medicated cattle feed	Original approval	558.635
April 7, 2025	141-588	Phibro Animal Health Corp. (066104)	V-MAX (virginiamycin) and RUMENSIN (monensin) Type A medicated articles to be used in the manufacture of Type B/C medicated cattle feeds	Original approval	558.635
April 8, 2025	141-587	Phibro Animal Health Corp. (066104)	V-MAX (virginiamycin), RUMENSIN (monensin), and OPTAFLEXX (ractopamine hydrochloride) Type A medicated articles to be used in the manufacture of Type B/C medicated cattle feeds	Original approval	558.635
April 8, 2025	141-521	Zoetis Inc (054771)	SIMPARICA TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) Chewable Tablets	Supplemental approval	520.2090
April 10, 2025	141-598	Dechra Ltd. (043264)	OTISERENE (marbofloxacin terbinafine dexamethasone otic suspension)	Original approval	524.1312
April 23, 2025	141-554	Boehringer Ingelheim Animal Health USA,	NEXGARD PLUS (afoxolaner,	Supplemental approval	520.35

		Inc. (000010)	moxidectin, and pyrantel chewable tablets)		
April 24, 2025	200-797	Huvepharma EOOD (016592)	COXIDIN (monensin) and BMD (bacitracin methylenedisalicylate) Type A medicated articles to be used in the manufacture of Type C medicated broiler feeds	Original approval as a generic copy of NADA 049-463	558.355
April 24, 2025	200-798	Huvepharma EOOD (016592)	COXIDIN (monensin) and FLAVOMYCIN (bambermycins) Type A medicated articles to be used in the manufacture of Type C medicated broiler feeds	Original approval as a generic copy of NADA 098-340	558.355
April 24, 2025	200-799	Huvepharma EOOD (016592)	COXIDIN (monensin) and BMD (bacitracin methylenedisalicylate) Type A medicated articles to be used in the manufacture of Type C medicated turkey feeds	Original approval as a generic copy of NADA 140-937	558.355
April 24, 2025	200-800	Huvepharma EOOD (016592)	COXIDIN (monensin) and FLAVOMYCIN (bambermycins) Type A medicated articles to be used in the manufacture of Type C medicated turkey feeds	Original approval as a generic copy of NADA 140-955	558.355
April 24, 2025	200-801	Huvepharma EOOD (016592)	COXIDIN (monensin) and INTEPRITY (avilamycin) Type A medicated articles to be used in the manufacture of Type C medicated broiler feeds	Original approval as a generic copy of NADA 141-465	558.68
April 24, 2025	200-802	Huvepharma EOOD (016592)	COXIDIN (monensin) and PENNITRACIN MD (bacitracin methylenedisalicylate) Type A medicated articles to be used in the manufacture of Type C medicated turkey feeds	Original approval as a generic copy of NADA 141-540	558.355
April 29, 2025	141-609	Genus plc (086205)	DELETION OF EXON 7 OF CD163 GENE IN DOMESTIC PIGS (Deletion of exon 7 of CD163 gene in domestic pigs)	Original approval	528.2000
April 29, 2025	141-600	Intervet (000061)	MOMETAMAX SINGLE (gentamicin, posaconazole, and	Original approval	524.1044j

			mometasone furoate otic suspension)		
May 21, 2025	141-581	Elanco US Inc. (058198)	CREDELIO QUATTRO (lotilaner, moxidectin, praziquantel, and pyrantel)	Supplemental approval	520.1287
June 24, 2025	200-812	Qilu Animal Health Products Co., Ltd. (086163)	Cefovecin Sodium for Injection (cefovecin sodium)	Original approval as a generic copy of NADA 141-285	522.311
June 27, 2025	200-813	Felix Pharmaceuticals Pvt. Ltd. (086101)	Clindamycin Hydrochloride Tablets (clindamycin hydrochloride)	Original approval as a generic copy of NADA 120-161	520.446
June 27, 2025	200-814	Felix Pharmaceuticals Pvt. Ltd. (086101)	Methimazole Coated Tablets (methimazole tablets)	Original approval as a generic copy of NADA 141-292	520.1375

¹See 21 CFR 510.600(c) for sponsor addresses.

² Approved in the first quarter of 2025.

³ Ibid.

II. Withdrawal of Approval of Applications

Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom (drug labeler code 043264) requested that FDA withdraw approval of one NADA listed in table 2 because the product was never manufactured or marketed. Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211 (drug labeler code 017033) requested that FDA withdraw approval of two ANADAs listed in table 2 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

Table 2.--Applications for Which Approval Was Voluntarily Withdrawn During April, May, and June 2025

Date of Withdrawal of Approval	Application No.	Product Name	21 CFR Section
May 27, 2025	008-760	ADRENOMONE (corticotropin) Injectable Solution	522.480
Do.	200-366	Carprofen Caplets (carprofen)	520.304
Do.	200-575	Carprofen Chewable Tablets (carprofen)	520.304

III. Changes of Sponsor

The sponsor of the approved application listed in table 3 has informed FDA that they have transferred ownership of, and all rights and interest in, this application to another sponsor. The regulation cited in table 3 is amended to reflect this action.

Table 3.--Applications for Which Ownership Was Transferred to Another Sponsor During April, May, and June 2025

Application No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR Section
200-512	TRIAMULOX (tiamulin hydrogen fumarate)	Zoetis Inc. (054771)	Phibro Animal Health Corp. (066104)	520.2455

IV. Change of Sponsor Address

Elanco US Inc., (drug labeler code 058198 in 21 CFR 510.600(c)) has informed FDA that it has changed its address. ECO LLC, (drug labeler code 066916 in 21 CFR 510.600(c)) also has informed FDA that it has changed its address. The entries in § 510.600(c) are amended to reflect these actions.

V. Technical Amendments

FDA is making the following amendments to improve the accuracy and readability of the animal drug regulations.

- 21 CFR 510.600(c) is amended to revise the entries for Elanco US Inc., and ECO, LLC in the lists of sponsors of approved applications, and to add entries for Genus plc. and Qilu Animal Health Products Co., Ltd.
- 21 CFR 510.600(c) is amended to change the name of “Sergeant's Pet Care Products, Inc.” to “Sergeant’s Pet Care Products LLC” in the lists of sponsors of approved applications.
- 21 CFR 522.1260(e)(2)(iii) is amended to clarify that the statement “Federal law restricts this drug to use by or on the order of a licensed veterinarian” applies to all drug products in that paragraph.

VI. 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)). Although deemed a rule under the FD&C Act, this document does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a “rule of particular applicability” and 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.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520, 522, 524, and 528

Animal drugs.

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, 528, 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:

a. In the table in paragraph (c)(1):

i. Revise the entries for “ECO LLC”, “Elanco US Inc.”;

ii. Add in alphabetical order entries for “Genus plc” and “Qilu Animal Health Products Co., Ltd.”; and

iii. Revise the entry for “Sergeant's Pet Care Products, Inc”;

b. In the table in paragraph (c)(2), add entries in numerical order for “086163” and “086205”; and revise the entries for “021091”, “058198”, and “066916”.

The revisions and additions 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
* * * * *	
ECO LLC, 506 Carnegie Centre, Suite 400, Princeton, NJ 08540	066916
Elanco US Inc., 450 Elanco Circle, Indianapolis, IN 46221	058198
* * * * *	
Genus plc, 1525 River Road, Deforest, WI 53532	086205
* * * * *	
Qilu Animal Health Products Co., Ltd., No. 10688, Wenliang Road, Dongjia Town, Licheng District Jinan, Shandong, 250100, China	086163
* * * * *	
Sergeant's Pet Care Products LLC, 10077 S. 134th St., Omaha, NE 68138	021091
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
021091	Sergeant's Pet Care Products LLC, 10077 S. 134th St., Omaha, NE 68138
* * * * *	
058198	Elanco US Inc., 450 Elanco Circle, Indianapolis, IN 46221
* * * * *	
066916	ECO LLC, 506 Carnegie Centre, Suite 400, Princeton, NJ 08540
* * * * *	
086163	Qilu Animal Health Products Co., Ltd., No. 10688, Wenliang Road, Dongjia Town, Licheng District Jinan, Shandong, 250100, China
* * * * *	
086205	Genus plc, 1525 River Road, Deforest, WI 53532
* * * * *	

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 § 520.35, revise paragraph (c)(2) by adding a sentence at the end of the paragraph to read as follows:

§ 520.35 Afoxolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) * * * For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

§ 520.304 [Amended]

5. In § 520.304, in paragraph (b)(1), remove the text “Nos. 017033, 054771, 055529, and 082983” and in its place add the text “Nos. 054771, 055529, and 082983”.

§ 520.446 [Amended]

6. In § 520.446, in paragraph (b)(2), remove the text “No. 051311” and in its place add the text “Nos. 051311 and 086101”.

§ 520.812 [Amended]

7. In § 520.812, in paragraph (b)(2), remove the text “Nos. 017033 and 086117” and in its place add the text “Nos. 017033, 086117, and 086194”.

8. In § 520.1287, revise the first sentence in paragraph (c)(2) to read as follows:

§ 520.1287 Lotilaner, moxidectin, praziquantel, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*), hookworm (fourth stage larvae, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*) infections. * * *

* * * * *

9. In § 520.1375, revise paragraph (b) and (c)(1) to read as follows:

§ 520.1375 Methimazole tablets.

* * * * *

(b) *Sponsors*, See Nos. 043264 and 086101 in § 510.600 of this chapter.

(c) * * *

(1) *Amount.* The starting dose is 2.5 mg every 12 hours. Following 3 weeks of treatment, the dose should be titrated to effect based on individual serum total T4 (TT4) levels and clinical

response. Dose adjustments should be made in 2.5 mg increments. The maximum total dosage is 20 mg per day divided, not to exceed 10 mg as a single administration.

* * * * *

10. In § 520.2090, revise paragraph (c)(2) to read as follows:

§ 520.2090 Sarolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and hookworm (L4, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*) infections. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, the prevention of *Dipylidium caninum* (tapeworm) infections as a direct result of killing *Ctenocephalides felis* vector fleas on the treated dog, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick) for one month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

11. In § 520.2455:

- a. Revise paragraph (b)(2); and
- b. Remove paragraph (b)(4).

The revision reads as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(2) No. 066104 for products described in paragraphs (a)(1) and (3) of this section.

(3) * * *

(c) * * *

* * * * *

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.311 [Amended]

13. In § 522.311, in paragraph (b), remove the text “*Sponsor*. See No. 054771 in § 510.600(c) of this chapter” and in its place add the text “*Sponsors*. See Nos. 054771 and 086163 in § 510.600(c) of this chapter”.

14. In § 522.480:

a. Revise paragraph (b); and

b. Remove paragraph (c)(3).

The revision reads as follows:

§ 522.480 Corticotropin.

* * * * *

(b) *Sponsor*. See No. 061133 in § 510.600(c) of this chapter.

(c) *Conditions of use--*

(1) * * *

(2) * * *

§ 522.970 [Amended]

15. In § 522.970, in paragraph (b)(1), remove the text “Nos. 000061, 055529, and 061133” and in its place add the text “Nos. 000061, 055529, 061133, and 069043”; and in

paragraph (b)(3), remove the text “Nos. 016592, 058198, and 069043” and in its place add the text “Nos. 016592 and 058198”.

16. In § 522.1260, revise paragraph (e)(2)(iii) to read as follows:

§ 522.1260 Lincomycin.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations*. Do not treat within 48 hours of slaughter. Federal law restricts this drug to use by or on the order of a licensed veterinarian

PART 524--OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: 21 U.S.C360b.

18. In Part 524, add § 524.1144j to read as follows:

§ 524.1144j Gentamicin, posaconazole, and mometasone furoate otic suspension.

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

(b) *Specifications*. A 0.8 milliliters (mL) dose delivers 6.88 milligrams (mg) gentamicin, 2.08 mg posaconazole, and 1.68 mg mometasone furoate.

(c) *Conditions of use*--This product should be administered by a veterinary professional.

(1) *Amount*. The dose volume is 0.8 mL per affected ear. Verify the tympanic membrane is intact prior to administration.

(2) *Indications for use*. For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius* and *Pseudomonas aeruginosa*)) in dogs.

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

§ 524.1146 [Amended]

19. In § 524.1146, in paragraph (b)(2), remove the text “and 058198” and in its place add the text “058198, and 061133”; and in paragraph (b)(3), remove the text “058198, and” and in its place add the text “058198, 061133, and”.

20. Add § 524.1312 to read as follows:

§ 524.1312 Marbofloxacin, terbinafine, and dexamethasone otic suspension.

(a) *Specifications*. Each single-use tube contains 15.1 milligrams (mg) marbofloxacin, 22.7 mg terbinafine, and 2.01 mg dexamethasone.

(b) *Sponsor*. See No. 043264 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount*. Administer one dose (1 tube) per affected ear once. Do not clean the ear canal for 30 days after administration.

(2) *Indications for use*. For the treatment of otitis externa associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*) in dogs.

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

PART 528--INTENTIONAL GENOMIC ALTERATIONS IN ANIMALS

21. The authority citation for part 528 continues to read as follows:

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

22. Add § 528.2000 to read as follows:

§ 528.2000 Deletion of exon 7 of CD163 gene in domestic pigs.

(a) *Specifications*. Deletion of one (heterozygous) or two (homozygous) copies of exon 7 of *CD163* gene1(abbreviated CD163ΔE7) in domestic pigs (*Sus scrofa domesticus*).

(b) *Sponsor*. See No. 086205 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Intended use*. Deletion of exon 7 of the *CD163* gene in domestic pigs (*Sus scrofa domesticus*) is intended to confer resistance to porcine reproductive

and respiratory syndrome virus (PRRSV) in homozygous pigs. Pigs carrying one or two copies of CD163^{ΔE7}, and their offspring, are intended for breeding or to be used as sources of food.

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

24. In § 558.68, revise paragraphs (e)(1)(ii) and (vii) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *

(1) * * *

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(ii) 13.6 to 40.9	Monensin, 90 to 110	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> , and as an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i>	Feed as the sole ration for 21 consecutive days. Feed to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with <i>Clostridium perfringens</i> . To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 18 days of age. Monensin as provided by Nos. 016592 or 058198 in § 510.600(c) of this chapter. See § 558.355(d).	016592 058198
* * * * *				

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* * * * *				
(vii) 100		For the treatment of swine dysentery and the control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i>	Feed as a sole ration for 3 weeks or until signs of disease (watery, mucoid, or bloody stools) disappear	066104
* * * * *				

25. In § 558.355, revise paragraphs (b)(2), (e)(1)(vii) and (xiv), and (e)(2)(ii) through (v)

to read as follows:

§ 558.355 Monensin.

* * * * *

(b) * * *

(2) No. 016592 for use of a Type A medicated article containing 90.7 grams monensin, USP, per pound as in paragraphs (e)(1)(i), (e)(1)(ii), (e)(1)(vii), (e)(1)(xiv), (e)(2), (e)(3), (e)(4)(v), and (e)(5) of this section.

* * * * *

(e) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(vii) 90 to 110	Bacitracin methylenedisalicylate, 5 to 25	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increase in rate of weight gain and improved feed efficiency	Feed as the sole ration. Monensin as provided by Nos. 016592 or 058198; bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198
* * * * *				
(xiv) 90 to 110	Bambermycins, 1 to 2	Broiler chickens: As an aid in the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> , and for increase in rate of weight gain and improved feed efficiency	Feed as the sole ration. Monensin as provided by Nos. 016592 or 058198; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198
* * * * *				

(2) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				

(ii) 54 to 90	Bacitracin methylenedisalicylate, 4 to 50	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. meleagrititis</i> , and <i>E. gallopavonis</i> , and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. The optimum level depends upon the severity of coccidiosis exposure. Monensin as provided by Nos. 016592 or 058198; bacitracin methylenedisalicylate as provided by Nos. 066104 or 069254 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198 069254
(iii) 54 to 90	Bacitracin methylenedisalicylate, 200	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. meleagrititis</i> , and <i>E. gallopavonis</i> , and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylenedisalicylate	Feed continuously as the sole ration. Monensin as provided by Nos. 016592 or 058198; bacitracin methylenedisalicylate as provided by No. 066104 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198
(iv) 54 to 90	Bambermycins, 1 to 2	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. meleagrititis</i> , and <i>E. gallopavonis</i> , and for improved feed efficiency	Feed continuously as the sole ration. Monensin as provided by Nos. 016592 or 058198; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198
(v) 54 to 90	Bambermycins, 2	Growing turkeys: For the prevention of coccidiosis caused by <i>Eimeria adenoeides</i> , <i>E. meleagrititis</i> , and <i>E. gallopavonis</i> , and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration. Monensin as provided by Nos. 016592 or 058198; bambermycins as provided by No. 016592 in § 510.600(c) of this chapter. See special labeling considerations in paragraph (d) of this section.	016592 058198

* * * * *

26. In § 558.635, add paragraphs (e)(3)(ii) through (viii) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(3) * * *

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * *				
(ii) 13.5 to 16.0	Monensin, 5 to 40	Growing beef steers and heifers fed in confinement for slaughter: For improved feed efficiency and reduction of incidence of liver abscesses	Feed at every feeding to provide 50 to 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104

(iii) 13.5 to 16.0	Monensin, 10 to 40	Growing beef steers and heifers fed in confinement for slaughter: For the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> , and reduction of incidence of liver abscesses	Feed at every feeding to provide 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of coccidiosis challenge, up to a maximum of 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104
(iv) 13.5 to 16.0	Monensin, 5 to 40; and lubabegron, 1.25 to 4.54	Growing beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, improved feed efficiency, and reduction of incidence of liver abscesses	Feed at every feeding as sole ration to provide 13 to 90 mg lubabegron/head/day, 50 to 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day during the last 14 to 91 days on feed. No additional improvement in feed efficiency has been shown from feeding monensin at levels greater than 30 g/ton (360 mg monensin/head/day). A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104
(v) 13.5 to 16.0	Monensin, 10 to 40; and lubabegron, 1.25 to 4.54	Growing beef steers and heifers fed in confinement for slaughter during the last 14 to 91 days on feed: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight, the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> , and reduction of incidence of liver abscesses	Feed at every feeding as sole ration to provide 13 to 90 mg lubabegron/head/day, 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of coccidiosis challenge, up to a maximum of 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day during the last 14 to 91 days on feed. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104
(vi) 13.5 to 16.0	Monensin, 10 to 40; and ractopamine hydrochloride, 8.2 to 24.6	Growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed: For increased rate of weight gain, improved feed efficiency, the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> , and reduction of incidence of liver abscesses	Feed at every feeding as a sole ration to provide 70 to 430 mg ractopamine hydrochloride/head/day, 0.14 to 0.42 mg monensin/lb of body weight per day, depending upon severity of coccidiosis challenge, up to a maximum of 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day during the last 28 to 42 days on feed. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104

(vii) 13.5 to 16.0	Monensin, 10 to 40; and ractopamine hydrochloride, 9.8 to 24.6	Growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed: For increased rate of weight gain, improved feed efficiency, increased carcass leanness, the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> , and reduction of incidence of liver abscesses	Feed at every feeding as a sole ration to provide 90 to 430 mg ractopamine hydrochloride/head/day, 0.14 to 0.42 mg monensin/lb of body weight per day, depending upon severity of coccidiosis challenge, up to a maximum of 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day during the last 28 to 42 days on feed. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. See § 558.355(d).	066104
(viii) 13.5 to 16.0	Monensin, 10 to 40; and ractopamine hydrochloride, not to exceed 800	Growing beef steers and heifers fed in confinement for slaughter during the last 28 to 42 days on feed: For increased rate of weight gain and improved feed efficiency, the prevention and control of coccidiosis caused by <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> , and reduction of incidence of liver abscesses when ractopamine hydrochloride is used as a top dress with rations containing monensin and virginiamycin	Feed a minimum of 1.0 lb per head per day of this Type C top-dress medicated feed to provide 70 to 400 mg/head/day ractopamine hydrochloride during the last 28 to 42 days on feed. Must be top dressed onto or mixed at feeding with a Type C medicated feed containing 10 to 40 g/ton monensin and 13.5 to 16 g/ton virginiamycin (90% dry matter basis), to provide 0.14 to 0.42 mg monensin/lb of body weight per day, depending upon severity of coccidiosis challenge, up to a maximum of 480 mg monensin/head/day and 85 to 240 mg virginiamycin/head/day. See § 558.355(d).	066104

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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