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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts, 516, 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2026-N-0002]

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

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), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (CNADAs) during January, February, and March 2026. 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*].

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SUPPLEMENTARY INFORMATION:

I. Approval of Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs, ANADAs, and CNADAs during January, February, and March 2026, 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, Conditional, and Supplemental Applications Approved During January, February, and March 2026

Date of approval	Application No.	Sponsor (drug labeler code[1])	Product name	Effect of the action	21 CFR sections
December 4, 2025	141-167	Intervet, Inc. (000061)	EXZOLT CATTLE-CA (fluralaner topical solution)	Conditional approval	516.900 556.290(b)(2)
January 9, 2026	200-828	Parnell Technologies Pty. Ltd. (068504)	nixiFLOR (florfenicol and flunixin meglumine) injectable solution	Original approval as a generic copy of NADA 141-299	522.956
January 9, 2026	141-615	Pegasus Laboratories, Inc. (055246)	KBROVET (potassium bromide chewable tablets)	Original approval	516.1858 520.1858
January 12, 2026	200-833	Felix Pharmaceuticals Pvt. Ltd. (086101)	Maropitant Citrate Chewable Tablets	Original approval as a generic copy of NADA 141-262	520.1315
January 13, 2026	200-831	Norbrook Laboratories Ltd.	Defendazole (fenbendazole)	Original approval as a generic copy of RLNAD NADA 128-620	520.905a
January 13, 2026	141-518	Intervet, Inc. (000061)	BRAVECTO PLUS (fluralaner and moxidectin topical solution)	Supplemental approval	524.1001
January 15, 2026	141-575	Boehringer Ingelheim Animal Health USA, Inc. (000010)	VETMEDIN Solution (pimobendan oral solution)	Supplemental approval	520.1782
January 20, 2026	141-554	Boehringer Ingelheim Animal Health USA, Inc. (000010)	NEXGARD PLUS (afoxolaner, moxidectin, and pyrantel chewable tablets)	Supplemental approval	520.35
January 29, 2026	200-761	Cronus Pharma Specialities India Private Ltd. (069043)	Cronoquin Tablets (marbofloxacin tablets)	Original approval as a generic copy of NADA 141-151	520.1310
January 30, 2026	200-830	Parnell Technologies Pty. Ltd. (068504)	Sevoflurane (sevoflurane)	Original approval as a generic copy NADA 141-103	529.2110
February 6, 2026	200-838	Felix Pharmaceuticals Pvt. Ltd. (086101)	Atipamezole Hydrochloride Injection (atipamezole hydrochloride) sterile injectable solution	Original approval as a generic copy of NADA 141-033	522.147
February 23, 2026	200-822	Baxter Healthcare Corporation (010019)	ANIRANE (isoflurane)	Original approval as a generic copy of NADA 135-773	529.1186
February 23, 2026	200-841	Felix Pharmaceuticals Pvt. Ltd. (086101)	Firocoxib Tablets for Horses (firocoxib)	Original approval as a generic copy of NADA 141-458	520.928
March 9, 2026	200-804	Cronus Pharma Specialities India Private Ltd. (069043)	Robenacoxib Injection (robenacoxib) Injectable Solution	Original approval as a generic copy of NADA 141-443	522.2075
March 10, 2026	095-735	Elanco, US Inc, (058198)	Rumensin 113 (monensin Type A medicated article)	Supplemental approval	558.355

March 16, 2026	141-599	Intervet, Inc. (000061)	BRAVECTO QUANTUM (fluralaner for extended-release injectable suspension)	Supplemental approval	522.998
March 23, 2026	141-616	Zoetis (054771)	DECTOMAX - CA1(doramectin injection)	Supplemental approval	516.570

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

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 two NADAs listed in table 2 because these products are no longer marketed. Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861 (drug labeler code 054925), requested that FDA withdraw approval of four ANADAs listed in table 2 because these products are no longer 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 January, February, and March 2026

Date of Withdrawal of Approval	Application No.	Product Name	21 CFR Section
February 27, 2026	047-955	ROMPUN 20 mg/mL	522.2662
February 27, 2026	200-408	Butorphanol Tartrate Injection 2 mg/mL	522.246
February 27, 2026	200-183	Vet Beta-Gen (gentamicin sulfate, betamethasone valerate)	524.1044b
February 27, 2026	200-188	Betagen Topical Spray (gentamicin sulfate, betamethasone valerate)	524.1044f
February 27, 2026	200-196	Miconosol (miconazole nitrate lotion/ spray 1%)	524.1443
February 27, 2026	200-229	TRI-OCTIC Ointment (gentamicin sulfate, betamethasone valerate, clotrimazole)	524.1044g

III. Changes of Sponsor

The sponsors of the approved applications listed in table 3 have informed FDA that they have transferred ownership of, and all rights and interest in, these applications to another sponsor. The regulations cited in table 3 are amended to reflect these actions.

Table 3--Applications for Which Ownership Was Transferred to Another Sponsor During January, February, and March 2026

Application No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR Section
200-771	Methimazole solution	Norbrook Laboratories Ltd. (055529)	Virbac AH, Inc. (051311)	520.1376
141-614	LAVERDIA (verdinexor tablets)	Anivive Lifesciences Inc. (086121)	Dechra, Ltd. (043264)	520.2700
200-683	CYCLEGUARD and MONOVET (melengestrol acetate Type A liquid	Zoetis (054771)	Phibro (066104)	558.342

	medicated article and monensin Type A medicated article			
139-235	BIO-COX and BACIFERM (salinomycin sodium Type A medicated article and bacitracin zinc Type A medicated article to be used in the manufacture of Type C medicated feeds	Do.	Do.	558.550
114-794	AMPROL HI-E and BACIFERM (amprolium with ethopabate Type A medicated article and bacitracin zinc Type A medicated article)	Do.	Do.	558.58
134-830	Coban and Albac (monensin Type A medicated article and bacitracin zinc Type A medicated article)	Do.	Do.	558.355

IV. Technical Amendments

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

- 21 CFR 520.522 is amended to revise language updated on the labeling for "Conditions for Use."
- 21 CFR 558.625 is amended to revise language updated on the labeling for "Indications for Use" and "Limitations" with ractopamine hydrochloride.

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)). 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 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

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 516, 520, 522, 524, 529, 556, and 558 are amended as follows:

PART 516--NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

1. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc-1, 360ccc-2, 371.

2. In § 516.570, revise paragraph (c)(2) to read as follows:

§ 516.570 Doramectin.

* * * * *

(c) * * *

(2) *Indications for use.* For prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis), and prevention of reinfestation for 21 days.

* * * * *

3. Add § 516.900 to subpart E to read as follows:

§ 516.900 Fluralaner.

(a) *Specifications*. Each milliliter (mL) of solution contains 50 milligrams (mg) of fluralaner

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

(c) *Conditions of use*--(1) *Amount*. 2.5 mg per kilogram (1.13 mg per one pound).

(2) *Indications for use*. For the prevention and treatment of infestations caused by New World screwworm (*Cochliomyia hominivorax*) larvae (myiasis) and treatment and control of cattle fever tick (*Rhipicephalus microplus*) in beef cattle 2 months of age and older and replacement dairy heifers less than 20 months of age.

(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Environmental temperature affects the withdrawal period. Cattle must not be slaughtered for human consumption within 98 days of treatment. If cattle are continuously exposed to temperatures at or above 60° F after product administration, then cattle may be slaughtered for human consumption 44 days after treatment. Violative residues may result if cattle are exposed to temperatures below 60° F after administration and are slaughtered at 44 days. Not for use in female dairy cattle 20 months of age or older, including dry dairy cows: use in these cattle may cause drug residues in milk and/or calves born to these cows or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

§ 516.1858 [Removed]

4. Remove § 516.1858.

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

6. In § 520.35, revise paragraph (c)(2) to read as follows:

§ 520.35 Afoxolaner, 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 adult hookworm (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*) and roundworm (*Toxocara canis* and

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

* * * * *

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

§ 520.43 Afoxolaner.

* * * * *

(c) * * *

(2) *Indications for use.* Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); and the treatment and control of *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (longhorned tick) 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.

* * * * *

8. Add § 520.136 to read as follows:

§ 520.136 Atinvicitinib tablets.

(a) *Specifications.* Each tablet contains 4.8, 7.2, 21.6, or 31.6 milligrams (mg) of atinvicitinib.

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

(c) *Conditions of use*--(1) *Amount.* Administer 0.36 to 0.54 mg atinvicitinib per pound (0.8 to 1.2 mg atinvicitinib per kilogram) of body weight, once daily, with food.

(2) *Indications for use.* For the control of pruritus associated with allergic dermatitis in dogs 6 months of age and older.

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

9. In § 520.522, revise paragraph (d)(1) introductory text to read as follows:

§ 520.522 Cyclosporine.

* * * * *

(d) * * *

(1) *Dogs*. Use capsules described in paragraph (a)(1) of this section or solution as described in paragraph (a)(2) of this section as follows:

* * * * *

10. In § 520.905a, revise paragraph (b) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) No. 000061 as in paragraph (e) of this section.

(2) No. 055529 as in paragraphs (e)(2) and (4) of this section.

* * * * *

11. In § 520.928, revise paragraph (b)(2) to read as follows:

§ 520.928 Firocoxib tablets.

* * * * *

(b) * * *

(2) Nos. 000010, 055246, and 086101 for use of the product described in paragraph (a)(2) of this section as in paragraph (c)(2) of this section.

* * * * *

§ 520.1310 [Amended]

12. In § 520.1310, in paragraph (b)(1), remove "Nos. 017033, 054771, and 086117" and in its place add "Nos. 017033, 054771, 069043, and 086117".

13. In § 520.1315, revise paragraphs (a) and (b) to read as follows:

§ 520.1315 Maropitant.

(a) *Specifications*. (1) Each tablet contains 16, 24, 60, or 160 milligrams (mg) maropitant as maropitant citrate.

(2) Each chewable tablet contains 16, 24, 60, or 160 mg maropitant as maropitant citrate.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter:

(1) Nos. 054771, 086101, and 086117 for use of the product described in paragraph (a)(1) of this section as in paragraph (c) of this section.

(2) No. 086101 for use of the product described in paragraph (a)(2) of this section as in paragraph (c) of this section.

* * * * *

§ 520.1376 [Amended]

14. In § 520.1376, in paragraph (b), remove "055529" and in its place add "051311".

15. In § 520.1782, revise paragraph (c)(2) to read as follows:

§ 520.1782 Pimobendan solution.

* * * * *

(c) * * *

(2) *Indications for use.* For the delay of onset of congestive heart failure (CHF) in dogs with Stage B2 preclinical myxomatous mitral valve disease (MMVD). Stage B2 preclinical MMVD refers to dogs with asymptomatic MMVD that have a moderate or loud mitral murmur due to mitral regurgitation and cardiomegaly. For the management of the signs of mild, moderate, or severe CHF in dogs due to clinical MMVD or dilated cardiomyopathy (DCM); for

use with concurrent therapy for CHF (*e.g.,* furosemide, etc.) as appropriate on a case-by-case basis.

* * * * *

16. Add § 520.1858 to read as follows:

§ 520.1858 Potassium bromide chewable tablets.

(a) *Specifications*. Each chewable tablet contains 250 or 500 milligrams (mg) potassium bromide.

(b) *Sponsor.* See No. 055246 in § 510.600(c) of this chapter.

(c) *Conditions of use*--(1) *Amount*. Administer 25 to 68 mg per kilogram (11 to 31 mg per pound) of body weight. The dosage should be adjusted based on monitoring of clinical response of the individual patient.

(2) *Indications for use*. For the control of seizures associated with idiopathic epilepsy in dogs.

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

§ 520.2700 [Amended]

17. In § 520.2700, in paragraph (b), remove "086121" and in its place add "043264".

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

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

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

§ 522.147 [Amended]

19. In § 522.147, in paragraph (b), remove "Nos. 015914, 052483, 068504, and 069043" and in its place add "Nos. 015914, 052483, 068504, 069043, and 086101".

20. In § 522.246:

a. Remove paragraph (b)(2);

b. Redesignate paragraph (b)(3) as paragraph (b)(2); and

c. Revise newly redesignated paragraph (b)(2).

The revision reads as follows:

§ 522.246 Butorphanol.

* * * * *

(b) * * *

(2) Nos. 000061, 017033, and 059399 for use of the product described in paragraph (a)(3) of this section as in paragraph (d)(3) of this section.

* * * * *

§ 522.533 [Amended]

21. In § 522.533, remove and reserve paragraphs (a)(2), (b)(2), and (c)(2).

§ 522.728 [Removed]

22. Remove § 522.728.

§ 522.956 [Amended]

23. In § 522.956, in paragraph (b), remove "No. 000061" and in its place add "Nos. 000061 and 068504".

24. In § 522.998, revise paragraph (c)(2) to read as follows:

§ 522.998 Fluralaner.

* * * * *

(c) * * *

(2) *Indications for use*. Kills adult fleas and for the treatment and prevention of flea infestations (*Ctenocephalides felis*); for the treatment and control of tick infestations *Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Rhipicephalus sanguineus* (brown dog tick), and *Amblyomma maculatum* (Gulf Coast tick) for 12 months in dogs and puppies 6 months of age and older; and for the treatment and control of *Amblyomma*

americanum (lone star tick) infestations for 8 months in dogs and puppies 6 months of age and older.

* * * * *

§ 522.2075 [Amended]

25. In § 522.2075, in paragraph (b), remove "No. 058198" and in its place add "Nos. 058198 and 069043".

§ 522.2662 [Amended]

26. In § 522.2662, in paragraph (b)(3), remove "Nos. 043264 and 061651" and in its place add "No. 061651".

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

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

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

28. In § 524.1001, revise paragraph (c)(2) to read as follows:

§ 524.1001 Fluralaner and moxidectin.

* * * * *

(c) * * *

(2) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati*, fourth-stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme*, fourth-stage larvae, immature adults, and adults); kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), *Haemaphysalis longicornis* (Asian longhorned tick), and *Amblyomma maculatum* (Gulf Coast tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

* * * * *

§ 524.1044b [Amended]

29. In § 524.1044b, in paragraph (b), remove “Nos. 000061 and 054925” and in its place add “No. 000061”.

§ 524.1044f [Amended]

30. In § 524.1044f, in paragraph (b), remove “Nos. 000061, 017033, 054925, 058005, and 058829” and in its place add “Nos. 000061, 017033, 058005, and 058829”.

31. In § 524.1044g:

a. Remove paragraph (b)(2);

b. Redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3), respectively, and

c. Revise paragraph (c)(1)(i).

The revision reads as follows:

§ 524.1044g Gentamicin, betamethasone, and clotrimazole ointment.

* * * * *

(c) * * *

(1) * * *

(i) From 7.5- or 15-g tubes; 10-, 12.5-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

* * * * *

§ 524.1443 [Amended]

32. In § 524.1443, in paragraph (b)(2), remove “Nos. 054925 and 058829” and in its place add “No. 058829”.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1186 [Amended]

34. In § 529.1186, in paragraph (b), remove “Nos. 017033, 054771, and 065085” and in its place add “Nos. 010019, 017033, 054771, and 065085”.

§ 529.2110 [Amended]

35. In § 529.2110, in paragraph (b), remove "Nos. 017033, 054771, and 065085" and in its place add "Nos. 017033, 054771, 065085, and 068504".

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

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

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

37. In § 556.290, add paragraph (b)(2) and revise paragraph (c) to read as follows:

§ 556.290 Fluralaner.

* * * * *

(b) * * *

(2) *Cattle*. (i) Liver (target tissue): 500 ppb.

(ii) Muscle: 350 ppb.

(c) *Related conditions of use*. See §§ 516.900 and 520.999 of this chapter.

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

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

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

39. In § 558.58, revise paragraph (e)(4) to read as follows:

§ 558.58 Amprolium and ethopabate.

* * * * *

(e) * * *

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(4) Amprolium 113.5 and ethopabate 36.3	Bacitracin (as feed grade bacitracin zinc) 4 to 50	2. Broiler chickens: As an aid in prevention of coccidiosis where severe exposure to coccidiosis from *Eimeria acervulina, E. maxima,* and *E. brunetti*	Feed as the sole ration from the time birds are placed on litter until past the time when coccidiosis is ordinarily a hazard, up to 16 weeks of age. If losses exceed 0.5% in a 2-day period, obtain an accurate diagnosis and follow the	066104

Amprolium and ethopabate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
		is likely to occur; for improved feed efficiency	instructions of your veterinarian or poultry pathologist. Do not feed to chickens producing eggs for human consumption. Not for chickens over 16 weeks of age. Do not feed as a treatment for outbreaks of coccidiosis. Do not change the litter while giving this feed unless absolutely necessary. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter.	
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* * * * *

40. In § 558.342, revise paragraph (e)(1)(iv) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(iv) 0.25 to 0.5	Monensin, 10 to 40	Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*	At the rate of 0.5 to 2.0 lb/head/day, a Type C top-dress medicated feed containing 0.25 to 2 g melengestrol acetate per ton must be top dressed onto or mixed at feeding with a Type C medicated feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d) of this chapter. Monensin as provided by No. 016592 or 058198; melengestrol	016592 066104 058198

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
			acetate as provided by No. 016952, 066104, or 058198 in § 510.600(c) of this chapter	

* * * * *

41. In § 558.355, revise paragraphs (a), (e)(1)(xi), (e)(4)(v) introductory text, and (e)(4)(v)(A) to read as follows:

§ 558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing 45, 60, 90.7, 110, or 113.4 grams monensin, USP, per pound.

* * * * *

(e) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(xi) 90 to 110	Bacitracin (as feed grade bacitracin zinc), 4 to 50	Broiler chickens: As an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain and improved feed efficiency	Feed as the sole ration. 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. In the absence of coccidiosis in broiler chickens, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain. Not for broiler breeder replacement chickens. Bacitracin zinc as provided by No. 054771 in 510.600(c) of this chapter	066104
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(4) * * *

Monensin amount	Indications for use	Limitations	Sponsor
* * * * * * *			
(v) 1,620 grams per ton of mineral granules as specified in paragraph (e)(4)(v)(A) of this section	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter) or in a dry lot and replacement beef and dairy heifers: For increased rate of weight gain, and for prevention and control of coccidiosis due to *Eimeria 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	016592 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 [2]	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 should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).		

Ingredient	Percent	International feed No.
[2] To provide 1,620 g monensin per ton, use 17.8 lb (0.89%) of a monensin Type A medicated article containing 90.7 g monensin per pound. If using a monensin Type A medicated article containing 113.4 grams monensin per pound, use 14.2 lb (0.71%), subtracting ground limestone.		

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42. In § 558.550, revise paragraph (e)(1)(v) to read as follows:

§ 558.550 Salinomycin.

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(e) * * *

(1) * * *

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* * * * * * *				
(v) 40 to 60	Bacitracin (as feed grade bacitracin zinc), 10 to 50	Broiler chickens: For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati,* and for increased rate of weight gain	Feed as the sole ration. The dosage of salinomycin sodium should be adjusted to meet the severity of coccidial challenge, which varies with environmental and management conditions. Do not feed to chickens producing eggs for human consumption. May be fatal if accidently fed to adult turkeys or horses. Do not use in Type C medicated feeds containing pellet binders. Bacitracin zinc as provided by No. 054771 in § 510.600(c) of this chapter	016592 066104
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43. In § 558.625, revise paragraphs (e)(1)(v), (x), and (xiii) to read as follows:

§ 558.625 Tylosin.

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(e) * * *

(1) * * *

Tylosin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
		* * * * * * *		
(v) 40 or 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, control of swine dysentery associated with *Brachyspira hyodysenteriae*, and control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 100 g of tylosin per ton of complete feed for at least three weeks, followed by 40 g tylosin per ton of complete feed until pigs reach market weight. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter	016592 054771 058198
		* * * * * * *		
(x) 40 to 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae*, and control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* immediately after medicating with tylosin in drinking water in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 40 to 100 grams of tylosin per ton of complete feed for 2 to 6 weeks immediately after medicating with tylosin in drinking water (250 mg tylosin per gallon) for 3 to 10 days as in § 520.2640(e)(3) of this chapter. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter	
		* * * * * * *		

(xiii) 100	Ractopamine hydrochloride, 4.5 to 9	For increased rate of weight gain, improved feed efficiency, increased carcass leanness, and control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis* in finishing swine weighing at least 150 lb and fed a complete ration containing at least 16% crude protein for the last 45 to 90 lb of gain prior to slaughter. Not for use in swine intended for breeding	Feed as the sole ration to finishing swine weighing at least 150 lb for the last 45 to 90 lb (group average) of weight gain prior to slaughter. Feed 100 g of tylosin per ton of complete feed for 21 days. Ractopamine hydrochloride use may increase the number of injured, lame, and/or fatigued pigs during marketing. Behavioral signs such as hyperactivity, anxiety, and aggression have been reported in pigs fed ractopamine hydrochloride. Tylosin phosphate as provided by Nos. 058198 and 016592; ractopamine hydrochloride as provided by Nos. 058198 and 054771 in § 510.600(c) of this chapter	016592 054771 058198

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Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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