DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2024–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 October, November, and December 2024. The animal drug regulations are also being amended to improve their accuracy and readability.

DATES: This rule is effective January 21, 2025.

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

SUPPLEMENTARY INFORMATION:

I. Approval of New Animal Drug Applications

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2024, 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 (FOIA Summaries) under the Freedom of Information Act (FOIA). These documents, along with marketing exclusivity and patent information, may be obtained at Animal Drugs @FDA: *https://animaldrugsatfda.fda.gov/adafda/views/#/search*.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2024 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Date of approval	File No.	Sponsor (drug labeler code [1])	Product name	Effect of the action	21 CFR section
October 7, 2024	141–554	Boehringer Ingelheim Animal Health USA, Inc. (000010)	NEXGARD PLUS (afoxolaner, moxidectin, and pyrantel chewable tablets).	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 1 month in dogs and puppies.	520.35
October 7, 2024	141–581	Elanco US Inc. (058198)	CREDELIO QUATTRO (lotilaner, moxidectin, praziquantel, and pyrantel chewable tablets.	Original approval for the prevention of heartworm disease and for the treatment and control of roundworm, hookworm, and tapeworm infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations and the treatment and control of tick infestations for 1 month in dogs and puppies.	520.1287
October 18, 2024	200–748	Huvepharma EOOD (016592)	PENNCHLOR (chlortetracycline Type A medicated article) and MONOVET (monensin) Type A medicated article) to be used in the manufacture of Type B and Type C medicated feeds.	Original approval as a generic copy of NADA 141–564.	558.128
October 23, 2024	141–589	Elanco US Inc. (058198)	EXPERIOR (lubabegron Type A medicated article) and MGA (melengestrol acetate Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Original approval for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and for reduction of ammonia gas emissions per pound of live weight and hot carcass weight in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.	558.330
October 25, 2024	141–590	Do.	EXPERIOR (lubabegron Type A medicated article), RUMENSIN (monensin Type A medicated article), and MGA (melengestrol acetate Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Original approval for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.	558.330

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2024 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Date of approval	File No.	Sponsor (drug labeler code [1])	Product name	Effect of the action	21 CFR section
October 25, 2024	141–591	Do.	EXPERIOR (lubabegron Type A medicated article), RUMENSIN (monensin Type A medicated article), TYLAN (tylosin Type A medicated article), and MGA (melengestrol acetate Type A medicated article) to be used in the manufacture of Type C medicated feeds.	Original approval for increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* and for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes* in growing beef heifers fed in confinement for slaughter during the last 14 to 91 days on feed.	558.625
November 6, 2024	141–521	Zoetis Inc. (054771)	SIMPARICA TRIO (sarolaner, moxidectin, and pyrantel chewable tablets).	Supplemental approval for the treatment and control of tick infestations with Asian longhorned tick for 1 month in dogs and puppies.	520.2090
November 13, 2024 ..	141–502	Do.	REVOLUTION PLUS (selamectin and sarolaner topical solution).	Supplemental approval for the prevention of tapeworm infections as a direct result of killing vector fleas on the treated cat for 1 month in cats and kittens.	524.2099
November 14, 2024 ..	200–803	Phibro Animal Health Corp. (066104)	PAQFLOR (florfenicol) Type A Medicated Article to be used in the manufacture of Type C medicated feeds.	Original approval as a generic copy of NADA 141–246.	558.261
November 18, 2024 ..	200–793	Parnell Technologies, Pty., Ltd. (068504)	PROPOFOLVET MULTIDOSE (propofol injectable emulsion).	Original approval as a generic copy of NADA 141–098.	522.2005
November 18, 2024 ..	200–805	Virbac AH, Inc. (051311)	MEL 500 (melengestrol acetate Type A liquid medicated article) to be used in the manufacture of Type C medicated feeds.	Original approval as a generic copy of NADA 039–402.	558.342
November 20, 2024 ..	200–636	Bimeda Animal Health, Ltd. (061133)	DORACIDE (doramectin topical solution)	Original approval as a generic copy of NADA 141–095.	524.770
November 22, 2024 ..	141–452	Zoetis Inc. (054771)	SIMPARICA (sarolaner) Chewable Tablet.	Supplemental approval for the treatment and control of tick infestations with Asian longhorned tick for 1 month in dogs and puppies.	520.2086
November 25, 2024 ..	141–532	Intervet, Inc. (000061)	BRAVECTO 1–MONTH (fluralaner) Chewable Tablet.	Supplemental approval for the treatment and control of Asian longhorned tick infestations for 1 month in dogs and puppies.	520.998
December 19, 2024 ..	141–043	Zoetis Inc. (054771)	SYNOVEX CHOICE and SYNOVEX PRIMER (trenbolone acetate and estradiol benzoate implants) Implants.	Supplemental approval of both products for increased rate of weight gain in growing beef steers and heifers on pasture (stocker, feeder, and slaughter).	522.2478

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

II. Withdrawal of Approval of New Animal Drug Applications

Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861 (drug labeler code (054925) requested that FDA withdraw approval of NADA 140–810 for DERMA–VET (nystatin, neomycin sulfate, thiostrepton, triamcinolone acetonide) Ointment because the product is no longer manufactured or marketed. Accordingly, approval of NADA 140–810 was withdrawn effective December 23, 2024. The animal drug regulations do not require amendment as the sponsor's drug labeler code is not codified in 21 CFR 524.1600a.

Mylan Institutional LLC, a Viatris Company, 3711 Collins Ferry Rd., Morgantown, WV 26505 (drug labeler code 063286) requested that FDA withdraw approval of ANADA 200–257 for Ketamine HCL (ketamine hydrochloride injection, USP) Injectable Solution because the product is no longer manufactured or marketed. Accordingly, approval of ANADA 200–257 was withdrawn effective June 29, 2023. The animal drug regulations do not require amendment as the sponsor's drug labeler code was removed from 21 CFR 522.1222 in a rule that published August 16, 2023 (88 FR 55559 at 55564).

III. Changes of Sponsor

The sponsors of the approved applications listed in table 2 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 2 are amended to reflect these actions.

TABLE 2—APPLICATIONS FOR WHICH OWNERSHIP WAS TRANSFERRED TO ANOTHER SPONSOR DURING OCTOBER, NOVEMBER, AND DECEMBER 2024

File No.	Product name	Transferring sponsor (drug labeler code)	New sponsor (drug labeler code)	21 CFR section
141–339	OVUGEL (triptorelin acetate) Gel	United-AH II LLC (051233)	Aurora Pharmaceutical, Inc. (051072)	529.2620
200–233	SUPERIORBUTE (phenylbutazone) Powder.	Superior Equine Pharmaceuticals, Inc. (027053)	Noble Pharma, LLC (086119)	520.1720e

IV. Change of Sponsor Address

Pharmacosmos, Inc. (drug labeler code 042552 in § 510.600(c)) has informed FDA that it has changed its address to 120 Headquarters Plz., Morristown, NJ 07960. The entries in § 510.600(c) are amended to reflect this action.

V. Technical Amendments

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

- § 510.600(c) is amended to remove entries for Superior Equine Pharmaceuticals, Inc. and United-AH II, LLC from the lists of sponsors of approved applications as these firms are no longer sponsors of an approved application.
- 21 CFR 522.2630(b) is amended to present the sequence of drug labeler codes for tulathromycin injectable solutions.

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 pursuant to the FD&C Act, this document does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a ''rule of particular applicability'' 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 529

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, 529, 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), revise the entry for ''Pharmacosmos, Inc.'' and remove the entries for ''Superior Equine Pharmaceuticals, Inc.'' and ''United-AH II, LLC''; and

■ b. In the table in paragraph (c)(2):

■ i. Remove the entry for ''027053'';

■ ii. Revise the entry for ''042552''; and

■ iii. Remove the entry for ''051233''.

The revision reads as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Pharmacosmos, Inc., 120 Headquarters Plz., Morristown, NJ 07960	042552
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
042552	Pharmacosmos, Inc., 120 Headquarters Plz., Morristown, NJ 07960.
* * * * * * *	

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 paragraphs (a) and (c)(2) to read as follows:

§ 520.35 Afoxolaner, moxidectin, and pyrantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 9.375 milligrams (mg) afoxolaner, 45 micrograms (mcg) moxidectin, and 18.75 mg pyrantel (as pamoate salt);

(2) 18.75 mg afoxolaner, 90 mcg moxidectin, and 37.5 mg pyrantel (as pamoate salt);

(3) 37.5 mg afoxolaner, 180 mcg moxidectin, and 75 mg pyrantel (as pamoate salt);

(4) 75 mg afoxolaner, 360 mcg moxidectin, and 150 mg pyrantel (as pamoate salt); or

(5) 150 mg afoxolaner, 720 mcg moxidectin, and 300 mg pyrantel (as pamoate salt).

* * * * *

(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), 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.

* * * * *

■ 5. In § 520.998, revise paragraph (c)(2)(ii) to read as follows:

§ 520.998 Fluralaner.

* * * * *

(c) * * *

(2) * * *

(ii) *Chewable tablets described in paragraph (a)(2) of this section.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*), and the treatment and control of tick infestations (*I. scapularis* (black-legged tick), *D. variabilis* (American dog tick), *R. sanguineus* (brown dog tick), and *H. longicornis* (Asian longhorned tick)) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 4.4 lb or greater; and for the treatment and control of *A. americanum* (lone star tick) infestations for 1 month in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

* * * * *

■ 6. Add § 520.1287 to read as follows:

§ 520.1287 Lotilaner, moxidectin, praziquantel, and pyrantel.

(a) *Specifications.* Each chewable tablet contains:

(1) 56.25 milligrams (mg) lotilaner, 0.056 mg moxidectin, 14.25 mg praziquantel, and 14.25 mg pyrantel (as pamoate salt);

(2) 112.5 mg lotilaner, 0.113 mg moxidectin, 28.5 mg praziquantel, and 28.5 mg pyrantel (as pamoate salt);

(3) 225 mg lotilaner, 0.225 mg moxidectin, 57 mg praziquantel, and 57 mg pyrantel (as pamoate salt);

(4) 450 mg lotilaner, 0.45 mg moxidectin, 114 mg praziquantel, and 114 mg pyrantel (as pamoate salt); or

(5) 900 mg lotilaner, 0.9 mg moxidectin, 228 mg praziquantel, and 228 mg pyrantel (as pamoate salt).

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

(c) *Conditions of use*—(1) *Amount.* Administer orally once a month, at the minimum dosage of 9 mg/lb (20 mg/kg) lotilaner, 0.009 mg/lb (0.02 mg/kg) moxidectin, 2.28 mg/lb (5 mg/kg) praziquantel, and 2.28 mg/lb (5 mg/kg) pyrantel (as pamoate salt).

(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 (adult *Uncinaria stenocephala*), and tapeworm (*Dipylidium caninum, Taenia pisiformis* and *Echinococcus granulosus*) infections. Kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 3.3 pounds or greater.

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

§ 520.1720e [Amended]

■ 7. In § 520.1720e, in paragraph (b)(1), remove the text ''027053'' and in its place add the text ''086119''.

■ 8. In § 520.2086, revise paragraphs (c)(1) and (2) to read as follows:

§ 520.2086 Sarolaner.

* * * * *

(c) * * *

(1) *Amount.* Administer orally once a month at the recommended minimum dosage of 0.91 mg/lb (2 mg/kg).

(2) *Indications for use.* Kills adult fleas, and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*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 1 month in dogs 6 months of age or 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.

* * * * *

■ 9. 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, 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 1 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.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 11. In § 522.2005:

■ a. Revise paragraph (b);

■ b. Revise the heading for paragraph (c);

■ c. Revise paragraph (c)(2); and

■ d. Add paragraph (d).

The revisions and addition read as follows:

§ 522.2005 Propofol.

* * * * *

(b) * * *

(1) No. 086064 for use as in paragraphs (c)(1), (c)(2)(i), (c)(3), (d)(1), (d)(2)(i), and (d)(3) of this section.

(2) No. 054771 for use as in paragraphs (c)(1), (c)(2)(ii), (c)(3), (d)(1), (d)(2)(ii), and (d)(3) of this section.

(3) Nos. 054771 and 068504 for use as in paragraphs (c)(1), (c)(2)(iii), and (c)(3) of this section.

* * * * *

(c) *Conditions of use in dogs*—

* * * * *

(2) *Indications for use.* (i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For induction of general anesthesia; for maintenance of anesthesia for up to 20 minutes; and for induction of general anesthesia followed by maintenance with an inhalant anesthetic.

(iii) For induction and maintenance of general anesthesia; and for induction of general anesthesia followed by maintenance with an inhalant anesthetic.

* * * * *

(d) *Conditions of use in* cats—(1) *Amount.* Administer by intravenous injection according to label directions. The use of preanesthetic medication reduces propofol dose requirements.

(2) *Indications for use.* (i) As a single injection to provide general anesthesia for short procedures; for induction and maintenance of general anesthesia using incremental doses to effect; and for induction of general anesthesia where maintenance is provided by inhalant anesthetics.

(ii) For induction and maintenance of general anesthesia; and for induction of general anesthesia followed by maintenance with an inhalant anesthetic.

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

■ 12. In § 522.2478, revise paragraph (d)(2) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

* * *

(d) * * *

(2) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter)*—(i) *Amounts and indications for use.* (A) An implant containing 50 mg trenbolone acetate and 7 mg estradiol benzoate as described in paragraph (a)(1)(i) of this section for increased rate of weight gain.

(B) An implant containing 100 mg trenbolone acetate and 14 mg estradiol benzoate as described in paragraph (a)(1)(ii) of this section for increased rate of weight gain.

(C) An extended-release implant containing 150 mg trenbolone acetate and 21 mg estradiol benzoate as described in paragraph (a)(2)(i) of this section for increased rate of weight gain for up to 200 days.

(ii) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant in growing beef steers and heifers on pasture (stocker, feeder, and slaughter). Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows.

* * * * *

§ 522.2630 [Amended]

■ 13. In § 522.2630, in paragraphs (b)(1) and (2), remove the text ''and 068504, 069043'' and add in its place the text ''068504, and 069043''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 15. In § 524.770, revise paragraph (b) to read as follows:

§ 524.770 Doramectin.

* * * * *

(b) *Sponsors.* See Nos. 051072, 054771, and 061133 in § 510.600(c) of this chapter.

* * * * *

■ 16. In § 524.2099, revise paragraph (c)(2) to read as follows:

§ 524.2099 Selamectin and sarolaner.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis,* the treatment and control of roundworm (*Toxocara cati*) and intestinal hookworm (*Ancylostoma tubaeforme*) infections, and the treatment and control of ear mite (*Otodectes cynotis*) infestations. 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 cat, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), and *Ixodes scapularis* (black-legged tick) for 1 month in cats and kittens 8 weeks and older, and weighing 2.8 pounds or greater.

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PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.2620 [Amended]

■ 18. In § 529.2620, in paragraph (b), remove the text ''051233'' and in its place add the text ''051072''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 20. In § 558.128, revise paragraphs (e)(4)(xxi) and (xxii) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xxi) 400 to 2,000 g/ton	Monensin, 15 to 84	Replacement beef and dairy heifers: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii*.	For replacement beef and dairy heifers not currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.. For replacement beef and dairy heifers currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone. This drug is not approved 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 in calves born to these cows. Monensin as provided by No. 058198 or 016592; chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	069254, 016592
(xxii) 400 to 2,000 g/ton.	Monensin, 15 to 400 ..	Replacement beef and dairy heifers: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline; and for increased rate of weight gain.	For replacement beef and dairy heifers not currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 100 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone to provide 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed.. For replacement beef and dairy heifers currently being fed monensin: Feed as the sole ration for not more than 5 days to provide 10 mg chlortetracycline per pound of body weight per day and 50 to 200 mg monensin per head per day in a minimum of 1 pound of Type C medicated feed. After 5 days, continue to feed monensin Type C medicated feed alone. This drug is not approved 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 in calves born to these cows. Monensin as provided by No. 058198 or 016592; chlortetracycline by No. 069254 in § 510.600(c) of this chapter.	0692544, 0165924
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■ 21. In § 558.261, revise paragraph (b) to read as follows:

§ 558.261 Florfenicol.

* * * * *

(b) *Sponsors.* See sponsor numbers as in § 510.600(c) of this chapter.

(1) No. 000061 for use of products described in paragraph (a) of this section as in paragraph (e) of this section.

(2) No. 066104 for use of product described in paragraph (a)(2) of this section as in paragraph (e)(2) of this section.

* * * * *

■ 22. In § 558.330:

■ a. Redesignate paragraph (d) as paragraph (e);

■ b. Add new paragraph (d); and

■ c. Revise newly redesignated paragraph (e).

The addition and revision read as follows:

§ 558.330 Lubabegron.

* * * * *

(d) *Special considerations.* Labeling shall bear the following caution statements:

(1) Lubabegron has not been approved for use in breeding animals because

safety and effectiveness have not been evaluated in these animals.

(2) Do not allow horses or other equines access to feed containing lubabegron.

(3) A decrease in dry matter intake may be noticed in some animals receiving lubabegron.

(e) *Conditions of use.* (1) It is used in cattle feed as follows:

Lubabegron (as lubabegron fumarate) in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 1.25 to 4.54		Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day during the last 14 to 91 days on feed. See special labeling considerations in paragraph (d) of this section..	058198
(ii) 1.25 to 4.54	Melengestrol acetate, 0.25 to 2 g/ton.	Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), and for reduction of ammonia gas emissions per pound of live weight and hot carcass weight during the last 14 to 91 days on feed.	Melengestrol acetate Type C top-dress medicated feed (0.5 to 2 lb(s) per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing 1.25 to 4.54 g/ton lubabegron to provide 0.25 to 0.5 mg melengestrol acetate and 13 to 90 mg lubabegron per head per day. Feed as the sole ration during the last 14 to 91 days on feed. See special labeling considerations in paragraph (d) of this section and in § 558.342(d). Lubabegron fumarate as provided by No. 058198; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter..	058198
(iii) 1.25 to 4.54	Monensin, 5 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight and for improved feed efficiency during the last 14 to 91 days on feed.	Feed continuously as sole ration to provide 13 to 90 mg lubabegron/head/day and 50 to 480 mg monensin/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). See special labeling considerations in paragraph (d) of this section and in § 558.355(d). Lubabegron fumarate as provided by No. 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter..	016592, 058198
(iv) 1.25 to 4.54	Monensin, 10 to 40	Beef steers and heifers fed in confinement for slaughter: For reduction of ammonia gas emissions per pound of live weight and hot carcass weight; and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* during the last 14 to 91 days on feed.	Feed continuously as the sole ration to provide 13 to 90 mg lubabegron/head/day and 0.14 to 0.42 mg monensin/lb body weight per day, depending upon severity of coccidiosis challenge, during the last 14 to 91 days on feed. See special labeling considerations in paragraph (d) of this section and in § 558.355(d). Lubabegron fumarate as provided by No. 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter..	016592, 058198
(v) 1.25 to 4.54	Monensin, 10 to 40 and melengestrol acetate, 0.25 to 2.	Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, and for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii* during the last 14 to 91 days on feed.	Melengestrol acetate Type C top-dress medicated feed (0.5 to 2 lb(s) per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing 1.25 to 4.54 g/ton lubabegron and 10 to 40 g/ton monensin, to provide 0.25 to 0.5 mg melengestrol acetate and 13 to 90 mg lubabegron per head per day, and 0.14 to 0.42 mg monensin per pound of body weight per day, depending upon severity of challenge, up to a maximum of 480 mg monensin per head per day. Feed as the sole ration during the last 14 to 91 days on feed. See special labeling considerations in paragraph (d) of this section, and in §§ 558.342(d) and 558.355(d). Lubabegron fumarate and monensin as provided by No. 058198; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter..	058198

(2) Lubabegron may also be used in combination with:

(i) [Reserved]

(ii) Tylosin as in § 558.625.

■ 23. In § 558.342:

■ a. Add paragraphs (b)(1) and (2); and

■ b. Revise paragraphs (e)(1)(i) and (ii).

The addition and revision read as follows:

§ 558.342 Melengestrol.

* * * * *

(b) * * *

(1) No. 054771 for use of products described in paragraph (a)(1) of this section:

(2) Nos. 016592, 051311, 054771, and 058198 for use of product described in paragraph (a)(2) of this section.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(i) 0.25 to 0.5		Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat)..	Administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day..	016592, 051311, 054771, 058198
(ii) 0.5		Heifers intended for breeding: For suppression of estrus (heat).	Administer 0.5 to 2.0 lb/head/day of Type C feed containing 0.25 to 1.0 mg melengestrol acetate/lb to provide 0.5 mg melengestrol acetate/head/day. Do not exceed 24 days of feeding.	016592, 051311, 054771, 058198
*	*	*	*	*

* * * * *

■ 24. In § 558.625:

■ a. Redesignate paragraphs (e)(2)(ix) through (xvii) as paragraphs (e)(2)(x) through (xviii); and

■ b. Add new paragraph (e)(2)(ix).

The addition reads as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	*	*
(ix) 8 to 10	Monensin, 10 to 40 plus lubabegron (as lubebegron fumarate), 1.25 to 4.54, plus melengestrol acetate, 0.25 to 2.0.	Growing beef heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, suppression of estrus (heat), for reduction of ammonia gas emissions per pound of live weight and hot carcass weight, for the prevention and control of coccidiosis caused by *Eimeria bovis* and *Eimeria zuernii,* and for reduction of incidence of liver abscesses associated with *Fusobacterium necrophorum* and *Arcanobacterium pyogenes* during the last 14 to 91 days on feed.	Feed as the sole ration during the last 14 to 91 days on feed. Melengestrol acetate Type C top-dress medicated feed (0.5 to 2.0 lb per head per day) must be top dressed onto or mixed at feeding with a Type C medicated feed containing 8 to 10 g/ton tylosin, 1.25 to 4.54 g/ton lubabegron, and 10 to 40 g/ton monensin, to provide 0.25 to 0.5 mg melengestrol acetate, 60 to 90 mg tylosin per head per day, 13 to 90 mg lubabegron per head per day, and 0.14 to 0.42 mg monensin per pound of body weight per day, depending on severity of challenge, up to 480 mg monensin per head per day. See special labeling considerations in §§ 558.330(d), 558.342(d), and 558.355(d). Tylosin as provided by No. 016592 or 058198; lubabegron fumarate and monensin as provided by No. 058198; melengestrol acetate as provided in No. 054771 in § 510.600(c) of this chapter.	058198
*	*	*	*	*

Dated: January 14, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–01226 Filed 1–17–25; 8:45 am]

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DEPARTMENT OF JUSTICE

Office of the Attorney General

28 CFR Part 50

[Docket No. OAG 174; AG Order No. 6148–2025]

RIN 1105–AB61

Processes and Procedures for Issuance and Use of Guidance Documents

AGENCY: Office of the Attorney General, Department of Justice.

ACTION: Final rule.

SUMMARY: This rule finalizes without change an interim final rule by which the Department of Justice (''Department'') removed amendments to its regulations that were made during 2020 pursuant to the now-revoked Executive Order 13891, which had imposed limitations on the use of Department guidance documents in criminal and civil enforcement actions brought by the Department.

DATES: This rule is effective January 17, 2025.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department