4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 524, and 558

[Docket No. FDA-2015-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) 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 May and June 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a nonsubstantive change. This technical amendment is being made to improve the accuracy of the regulations.

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

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SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect

approval actions for NADAs and ANADAs during May and June 2015, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During May and June 2015

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Sections	FOIA Summary	NEPA Review
141-417	Bayer HealthCare LLC Animal Health Division P.O. Box 390 Shawnee Mission, KS 66201	CORAXIS (moxidectin) Topical Solution for Dogs	Original approval for the prevention of heartworm disease, and for the treatment and control of intestinal hookworm, roundworm and whipworm infections in dogs	524.1450	yes	CE[1,2]
141-188	Merial Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640	MARQUIS (ponazuril) Oral Paste	Supplemental approval of a revised dosage that includes a loading dose on the first day of treatment	520.1855	yes	CE[1,2]
141-262	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	CERENIA (maropitant citrate) Tablets	Supplemental approval extending duration of daily administration until resolution of acute vomiting	520.1315	yes	CE[1,2]
141-291	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom	VETORYL (trilostane) Capsules	Supplemental approval of a 5-milligram capsule size	520.2598	no	CE[1,2]
141-278	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) Type A medicated articles	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to cattle fed in confinement for slaughter	558.665	yes	CE[1,3]

141-282	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) plus MGA (melengestrol acetate) Type A medicated articles	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to heifers fed in confinement for slaughter	558.665	yes	CE[1,3]
141-284	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	ZILMAX (zilpaterol hydrochloride) plus MGA (melengestrol acetate) Type A medicated articles	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds to heifers fed in confinement for slaughter	558.665	yes	CE[1,3]
200-497	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland	LOXICOM (meloxicam) 1.5 mg/mL Oral Suspension	Original approval as a generic copy of NADA 141-213	520.1367	yes	CE[1,3]
200-580	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TYLOVET (tylosin phosphate) plus SACOX (salinomycin sodium) Type C medicated feeds	Original approval as a generic copy of NADA 141-198	558.550[4]	yes	CE[1,3]

[1]The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.

[2]CE granted under 21 CFR 25.33(d)(1).

[3]CE granted under 21 CFR 25.33(a)(1).

[4]The regulation does not require amendment.

Also, the animal drug regulations are being amended to reflect approved labeling for hand feeding bambermycins medicated cattle feed. This technical amendment is being made to improve the accuracy of the regulations.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Parts 520 and 524

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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 524, and 558 are amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. In § 520.1315, revise paragraph (c)(1) to read as follows:

§ 520.1315 Maropitant.

* * * * *

(c) * * *

(1) Indications for use and amount. (i) For prevention of acute vomiting in dogs 2 to 7 months of age, administer a minimum dose of 2.0 mg per kilogram (/kg) body weight once daily

for up to 5 consecutive days.

(ii) For prevention of acute vomiting in dogs 7 months of age and older, administer a minimum dose of 2.0 mg/kg body weight once daily until resolution of acute vomiting.

(iii) For prevention of vomiting due to motion sickness in dogs 4 months of age and older, administer a minimum of 8.0 mg/kg body weight once daily for up to 2 consecutive days.

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§ 520.1367 [Amended]

3. In § 520.1367, in paragraph (b)(2), remove "No. 013744" and in its place add "Nos. 013744 and 055529".

4. In § 520.1855, revise paragraph (c)(1) to read as follows:

§ 520.1855 Ponazuril.

* * * * *

(c) * * *

(1) Amount. Administer orally 15 mg per kilogram (kg) (6.81 mg per pound (lb)) body weight as the first dose, followed by 5 mg/kg (2.27 mg/lb) body weight once daily for a period of 27 additional days.

* * * * *

§ 520.2598 [Amended]

5. In § 520.2598, in paragraph (a), remove "10, 30, or 60 milligrams" and in its place add "5, 10, 30, 60, or 120 milligrams".

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

6. The authority citation for 21 CFR part 524 continues to read as follows:

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

7. In § 524.1450, and revise paragraphs (a), (b), and (d), and remove paragraph (e).

The revisions read as follows:

§ 524.1450 Moxidectin.

(a) Specifications. Each milliliter of solution contains:

(1) 5 milligrams (mg) moxidectin (0.5 percent solution).

(2) 25 mg moxidectin (2.5 percent solution).

(b) Sponsors. See sponsor numbers in § 510.600 of this chapter:

(1) No. 000010 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section;

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

* * * * *

(d) Conditions of use--(1) Cattle--(i) Amount. Administer topically 0.5 mg per kilogram (kg) of body weight.

(ii) Indications for use. Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (Ostertagia ostertagi (adult and L4, including inhibited larvae), Haemonchus placei (adult and L4), Trichostrongylus axei (adult and L4), T. colubriformis (adult and L4), Cooperia oncophora (adult and L4), C. pectinata (adult), C. punctata (adult and L4), C. spatulata (adult), C. surnabada (adult and L4), Bunostomum phlebotomum (adult), Oesophagostomum radiatum (adult and L4), Nematodirus helvetianus (adult and L4)); lungworms (Dictyocaulus viviparus (adult and L4)); cattle grubs (Hypoderma bovis, H. lineatum); mites (Chorioptes bovis, Psoroptes ovis (P. communis var. bovis)); lice (Linognathus vituli, Haematopinus eurysternus, Solenopotes capillatus, Bovicola (Damalinia)

bovis); and horn flies (Haematobia irritans). To control infections and to protect from reinfection with H. placei for 14 days after treatment, O. radiatum and O. ostertagi for 28 days after treatment, and D. viviparus for 42 days after treatment.

(iii) Limitations. A withdrawal period has not been established for this product on preruminating calves. Do not use on calves to be processed for veal. See § 500.25 of this chapter.

(2) Dogs--(i) Amount. Administer topically a minimum of 1.1 mg per pound (lb) (2.5 mg/kg) of body weight, once monthly using the appropriate preloaded applicator tube.

(ii) Indications for use. For the prevention of heartworm disease caused by Dirofilaria immitis, as well as the treatment and control of intestinal hookworm (Ancylostoma caninum (adult, immature adult, and L4 larvae) and Uncinaria stenocephala (adult, immature adult, and L4 larvae)), roundworm (Toxocara canis (adult and L4 larvae) and Toxascaris leonina (adult)), and whipworm (Trichuris vulpis (adult)) infections in dogs and puppies that are at least 7 weeks of age and that weigh at least 3 lbs.

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

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

8. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.95 [Amended]

9. In § 558.95, in the table in paragraph (d)(4)(ii), in the "Bambermycins in grams/ton" column, remove "2 to 40" and in its place add "2 to 80"; and in the "Limitations" column, remove the first sentence and in its place add "Feed continuously on a hand-fed basis at a rate of

10 to 40 milligrams per head per day in 1 to 10 pounds of supplemental Type C medicated feed.".

10. In § 558.665, revise paragraphs (d)(2) and (e) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(d) * * *

(2) Labeling of Type A medicated articles and Type B medicated feeds used to manufacture complete Type C medicated feeds shall bear the caution statement in paragraph (d)(3) of this section.

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

Zilpaterol hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(1) 6.8	…….	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061
(2) 6.8	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin	000061 000986

		during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii.	per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.355(d) of this chapter. Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	
(3) 6.8	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. Melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	000061 000986
(4) 6.8	Monensin 10 to 40 plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up	000061 000986

		bovis and E. zuernii; and for suppression of estrus (heat).	to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	
(5) 6.8	Monensin 10 to 40, plus tylosin 8 to 10	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; and for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes.	Feed continuously as the sole ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.355(d) and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter.	000061 016592
(6) 6.8	Monensin	Heifers fed in confinement for	Feed continuously as the sole	000061

	10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes; and for suppression of estrus (heat).	ration during the last 20 to 40 days on feed to provide 60 to 90 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d), 558.355(d), and 558.625(c) of this chapter. Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592; and melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	000986 016592
(7) 6.8 to 24	…….	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed.	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section.	000061

(8) 6.8 to 24	Monensin 10 to 40	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii.	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.355(d) of this chapter. Monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000061
(9) 6.8 to 24	Melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraph § 558.342(d) of this part. Melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter.	000061
(10) 6.8 to 24	Monensin 10 to 40, plus melengestrol acetate to	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin	000061

	provide 0.25 to 0.5 mg/head/day	confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; and for suppression of estrus (heat).	per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d) and 558.355(d) of this chapter. Monensin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter.	
(11) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; and for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes.	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.355(d) and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	000061

(12) 6.8 to 24	Monensin 10 to 40, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in cattle fed in confinement for slaughter during the last 20 to 40 days on feed; for prevention and control of coccidiosis due to Eimeria bovis and E. zuernii; for reduction of incidence of liver abscesses caused by Fusobacterium necrophorum and Arcanobacterium (Actinomyces) pyogenes; and for suppression of estrus (heat).	Feed continuously during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day and 0.14 to 0.42 mg monensin per pound of body weight per day depending on the severity of the coccidiosis challenge, up to 480 mg/head/day monensin. Withdrawal period: 3 days. See paragraph (d) of this section. See paragraphs §§ 558.342(d), 558.355(d), and 558.625(c) of this chapter. Monensin and tylosin as provided by No. 000986; melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter.	000061

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