4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2016-N-0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, 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 January and February 2016. 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 changes of sponsorship of applications that occurred in January and February.

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

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5689, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January and February 2016, 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 January and February 2016

File No.	Sponsor	Product Name	Action	21 CFR Section	FOIA Summary	NEPA Review
141-444	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW United Kingdom	ZYCORTAL Suspension (desoxycorticosterone pivalate injectable suspension)	Original approval for use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's disease)	522.535	yes	CE[1,2]
141-448	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601	THYRO-TABS CANINE (levothyroxine sodium tablets)	Original approval for replacement therapy for diminished thyroid function in dogs	520.1248	yes	CE[1,2]
141-452	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	SIMPARICA (sarolaner) Chewables	Original approval for killing adult fleas, and for the treatment and prevention of flea infestations and the treatment and control of tick infestations in dogs	520.2086	yes	CE[1,2]
141-263	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	CERENIA (maropitant citrate) Injectable Solution	Supplemental approval providing for intravenous administration in dogs and cats	522.1315	yes	CE[1,2]
141-449	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940	SAFE-GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate	Supplemental approval for the treatment and control of certain nematode worms in swine, except for nursing piglets; and of a revised tolerance in swine liver	520.905a, 556.275	yes	EA/FONSI[3]
200-600	ECO LLC, 344 Nassau St., Princeton, NJ 08540	WORMX (pyrantel pamoate) Flavored Tablets	Original approval as a generic copy of NADA 139-191	520.2041	yes	CE[1,2]

[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]The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

Also, FDA is amending the regulations to reflect the approval of several minor supplemental applications that revised classes of food-producing animals in indications and in food safety warnings for decoquinate and robenidine in medicated feeds. A food safety precautionary statement has also been revised for use of monensin in medicated chicken feed.

II. Changes of Sponsorship

Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product Name	21 CFR Section
006-391	S.Q. (sulfaquinoxaline) 40% Medicated Feed	558.586
006-677	S.Q. (sulfaquinoxaline) 20% Solution	520.2325a
007-087	Sulfaquinoxaline Solubilized	520.2325a
033-157	SPECTAM Scour Halt (spectinomycin dihydrochloride pentahydrate) Solution	520.2123c
040-040	SPECTAM (spectinomycin) Injectable Solution	522.2120
048-287	Oxytetracycline-50 (oxytetracycline hydrochloride) Injection	522.1662a
065-110	PEN-G-MAX (penicillin G procaine) Injectable Suspension	522.1696b
065-498	DUAL-CILLIN (benzathine penicillin G and procaine penicillin G) Injectable Suspension	522.1696a
119-142	PVL Iron Dextran (iron hydrogenated dextran) Injectable	522.1182
128-089	ZONOMETH (dexamethasone) Injectable Solution	522.540
140-270	SULFASURE SR (sulfamethazine) Sustained-Release Cattle Bolus	520.2260b
200-068	Oxytetracycline Hydrochloride 100 mg/mL Injection	522.1662a
200-108	Dexamethasone Injectable Solution	522.540
200-118	Neomycin (neomycin sulfate) Oral Solution	520.1484
200-123	MAXIM-200 (oxytetracycline) Injection	522.1660a
200-147	GENTA-JECT (gentamicin sulfate) Injectable Solution	522.1044
200-153	NEO 200 (neomycin sulfate) Oral Solution	520.1484
200-162	Tripelennamine Hydrochloride Injection	522.2615
200-174	Gentamicin Sulfate Pig Pump Oral Solution	520.1044b
200-177	Sulfadimethoxine Injection 40%	522.2220
200-192	Sulfadimethoxine 12.5% Oral Solution	520.2220a
200-219	Ivermectin Pour-On for Cattle	524.1193
200-463	Amprolium-P 9.6% Oral Solution	520.100

Also, Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the

following applications to Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666.

File No.	Product Name	21 CFR Section
038-200	OXY WS (oxytetracycline) Soluble Antibiotic	520.1660d
065-178	FERMYCIN (chlortetracycline) Soluble	520.441
065-496	Tetracycline Soluble Powder	520.2345d

In addition, Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product Name	21 CFR Section
006-891	SUL-Q-NOX (sulfaquinoxaline) Soluble Powder	520.2325a
065-140	TET-SOL 324 (tetracycline hydrochloride) Soluble Powder	520.2345d
100-094	POULTRYSULFA (sulfamerazine, sulfamethazine, and sulfaquinoxaline) Soluble Powder	520.2218
128-686	BIO-COX (salinomycin) Type A Medicated Article	558.550
130-435	OXY-TET (oxytetracycline hydrochloride) Soluble Powder/Solution	520.1660d
134-284	BIO-COX / FLAVOMYCIN (bambermycins)	558.550
200-106	R-PEN (Penicillin G potassium) Soluble Powder	520.1696b
200-130	NEO-SOL 50 (neomycin sulfate) Soluble Powder	520.1484
200-189	Lincomycin Soluble Powder	520.1263c
200-441	AUREOMYCIN (chlortetracycline) Soluble Powder	520.441

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Technical Amendments

FDA has noticed that it failed to amend all necessary regulations to reflect the change of sponsorship of an oxytetracycline soluble powder (80 FR 13226, March 13, 2015). At this time, we are amending 21 CFR 529.1660 to include the drug labeler code for the new sponsor. This action is being taken to improve the accuracy of the regulations.

FDA has also noticed that in § 558.355 (21 CFR 558.355) use of bacitracin methylenedisalicylate at 100 to 200 grams/ton in combination with monensin in broiler and replacement chicken feeds was codified in error for NADA 141-140 (66 FR 13236, March 5,

2001). At this time, § 558.355 is amended by removing paragraphs (f)(1)(xxx) and (f)(4)(v). In addition, paragraph (f)(4)(iv), a remnant of a previous technical amendment (79 FR 10963, February 27, 2014), is also being removed. We have also noticed that certain paragraphs describing approved conditions of use were removed in error from § 558.355 during codification of a supplemental application to NADA 138-456 that increased the dose range for monensin used in combination with bacitracin methylenedisalicylate in broiler chicken feed (57 FR 6554, February 26, 1992). At this time, § 558.355 is amended by adding paragraphs (f)(1)(xxiv)(a) and (b). These actions are being taken to improve the accuracy of the regulations.

FDA has noticed that in error we removed the approved conditions of use for gleptoferron, an injectable iron used to prevent anemia in young piglets. At this time, 21 CFR 522.1055 is being added. This action is being taken 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, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.100 [Amended]

2. In § 520.100, remove and reserve paragraph (b)(3).

3. In § 520.441, revise paragraph (b)(1), remove paragraph (b)(2); redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3); and revise newly redesignated paragraph (b)(2).

The revisions read as follows:

§ 520.441 Chlortetracycline powder.

* * * * *

(b) * * *

(1) Nos. 000010, 016592, 054771, and 069254 for use as in paragraph (d) of this section.

(2) No. 066104 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

* * * * *

4. In § 520.905a, in paragraph (a), remove "paragraph (e)(5)" and in its place add "paragraphs (e)(5) and (6)"; and add paragraph (e)(6) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(6) Swine, except for nursing piglets--(i) Amount. Administer orally via the drinking water at a daily dose of 2.2 mg/kg of body weight (1.0 mg/lb) for 3 consecutive days.

(ii) Indications for use. For the treatment and control of lungworms: Adult Metastrongylus apri, adult M. pudendotectus; gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large roundworms (Ascaris suum); nodular worms (Oesophagostomum dentatum, O. quadrispinulatum); small stomach worms (Hyostrongylus rubidus): Adult and larvae (L2, L3, L4 stages--intestinal mucosal forms) whipworms (Trichuris suis); and kidney worms: Adult and larvae Stephanurus dentatus.

(iii) Limitations. Swine intended for human consumption must not be slaughtered within 2 days from the last treatment.

§ 520.1044b [Amended]

5. In § 520.1044b, in paragraph (b), remove "000859" and in its place add "016592".

6. Add § 520.1248 to read as follows:

§ 520.1248 Levothyroxine.

(a) Specifications. Each tablet contains 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, or 1.0 milligrams (mg) levothyroxine sodium.

(b) Sponsor. See No. 061690 in § 510.600(c) of this chapter.

(c) Conditions of use--(1) Amount. Administer by mouth 0.1 mg/10 pounds of body weight (0.022 mg/kilogram) as a single dose every 24 hours or as a divided dose every 12 hours.

(2) Indications for use. For replacement therapy for diminished thyroid function in dogs.

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

7. In § 520.1263c, revise paragraph (b) to read as follows:

§ 520.1263c Lincomycin powder.

* * * * *

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

(1) No. 016592 for use as in paragraph (d) of this section.

(2) Nos. 054925, 061623, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

§ 520.1484 [Amended]

8. In § 520.1484, in paragraph (b)(2), remove "054771" and in its place add "016592, 054771,"; and in paragraph (b)(3), remove "000859" and in its place add "016592".

§ 520.1660d [Amended]

9. In § 520.1660d, in paragraph (b)(2), remove "054771" and in its place add "016592"; and in paragraph (b)(3), remove "054628" and in its place add "066104".

§ 520.1696b [Amended]

10. In § 520.1696b, in paragraph (b), in numerical order add "016592".

§ 520.1705 [Amended]

11. In § 520.1705, in paragraph (a), remove "pergolide mesylate" and in its place add "pergolide (as pergolide mesylate)".

§ 520.2041 [Amended]

12. In § 520.2041, in paragraph (b), remove "Nos. 017135 and 051311" and in its place add "Nos. 017135, 051311, and 066916".

13. Add § 520.2086 to read as follows:

§ 520.2086 Sarolaner.

(a) Specifications. Each chewable tablet contains 5, 10, 20, 40, 80, or 120 milligrams (mg) sarolaner.

(b) Sponsor. See No. 054771 in § 510.600(c) of this chapter.

(c) Conditions of use in dogs--(1) Amount. Administer orally once a month at the recommended minimum dosage of 0.9 mg/lb (2 mg/kg).

(2) Indications for use. Kills adult fleas, and 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), and Rhipicephalus sanguineus (brown dog tick)) for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or more.

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

§ 520.2123c [Amended]

14. In § 520.2123c, in paragraph (b), remove "000859" and in its place add "016592".

§ 520.2218 [Amended]

15. In § 520.2218, in paragraph (b), remove "054771" and in its place add "016592".

§ 520.2220a [Amended]

16. In § 520.2220a, in paragraph (b)(1), remove "000859" and in its place add "016592".

§ 520.2260b [Amended]

17. In § 520.2260b, in paragraph (f)(1), remove "000859" and in its place add "016592".

§ 520.2325a [Amended]

18. In § 520.2325a, in paragraph (a)(1), remove "000859" and in its place add "016592"; and in paragraph (a)(3), remove "No. 054771" and in its place add "Nos. 016592 and 054771".

19. In § 520.2345d, in paragraph (b)(2), remove "054628" and in its place add "066104"; in paragraph (b)(3), remove "No. 054771" and in its place add "Nos. 016592 and 054771"; and

revise the first sentence in paragraph (d)(1)(iii) and paragraph (d)(2)(iii) to read as follows:

§ 520.2345d Tetracycline powder.

* * * * *

(d) * * *

(1) * * *

(iii) Limitations. Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 066104 and within 5 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline. * * *

(2) * * *

(iii) Limitations. Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 066104 and within 4 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

* * * * *

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

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

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

21. Revise § 522.535 to read as follows:

§ 522.535 Desoxycorticosterone.

(a) Specifications. Each milliliter of suspension contains 25 milligrams (mg) of desoxycorticosterone pivalate.

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

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(ii), (c)(2)(ii), and (c)(3) of this section.

(c) Conditions of use--(1) Amount. (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) Indications for use--(i) For use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's Disease).

(ii) For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

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

§ 522.540 [Amended]

22. In § 522.540, in paragraphs (a)(2)(i) and (d)(2)(i), remove "000859" and in its place add "016592".

§ 522.1044 [Amended]

23. In § 522.1044, in paragraph (b)(4), remove "000859" and in its place add "016592".

24. Add § 522.1055 to read as follows:

§ 522.1055 Gleptoferron.

(a) Specifications. Each milliliter contains the equivalent of 200 milligrams (mg) of elemental iron as gleptoferron (complex of ferric hydroxide and dextran glucoheptonic acid).

(b) Sponsor. See No. 059120 in § 510.600(c) of this chapter.

(c) Conditions of use. It is used in young piglets as follows:

(1) Amounts and indications for use--(i) Administer 200 mg of elemental iron intramuscularly on or before 3 days of age for prevention of iron deficiency anemia.

(ii) Administer 200 mg of elemental iron intramuscularly for treatment of iron deficiency anemia.

(2) [Reserved]

§ 522.1182 [Amended]

25. In § 522.1182, in paragraph (b)(6), remove "000859" and in its place add "016592"; and remove paragraph (b)(8).

§ 522.1315 [Amended]

26. In § 522.1315, in paragraphs (c)(1)(i) and (c)(2)(i), remove "subcutaneous injection" and in its place add "subcutaneous or intravenous injection".

§ 522.1660a [Amended]

27. In § 522.1660a, in paragraph (b), remove "000859" and in its place add "016592".

§ 522.1662a [Amended]

28. In § 522.1662a, in paragraphs (h)(2) and (i)(2), remove "000859" and in its place add "016592".

§ 522.1696a [Amended]

29. In § 522.1696a, in paragraph (b)(2), remove "000859" and in its place add "016592".

§ 522.1696b [Amended]

30. In § 522.1696b, in paragraph (b)(1), remove "000859" and in its place add "016592".

§ 522.2120 [Amended]

31. In § 522.2120, in paragraph (b), remove "000859" and in its place add "016592".

§ 522.2220 [Amended]

32. In § 522.2220, in paragraph (b)(3), remove "000859" and in its place add "016592".

§ 522.2615 [Amended]

33. In § 522.2615, in paragraph (b), remove "000859" and in its place add "016592".

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

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

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

§ 524.1193 [Amended]

35. In paragraph (b)(2) of § 522.1193, remove "000859" and in its place add "016592".

§ 524.1484k [Amended]

36. In § 522.1484k, revise the section heading to read: Neomycin and prednisolone suspension.

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1660 [Amended]

38. In § 529.1660, in paragraph (b)(2), remove "048164, 054771, and 061623" and in its place add "054771, 061623, and 069254".

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

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

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

40. In § 556.275, in paragraph (b)(2)(i), remove "6 ppm" and in its place add "3.2 ppm"; redesignate paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and add new paragraph (b)(3) and paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(3) Chickens--(i) Liver (the target tissue). The tolerance for fenbendazole sulfone (the marker residue) is 5.2 ppm.

(ii) [Reserved]

* * * * *

(c) Related conditions of use. See §§ 520.905a, 520.905c, 520.905d, 520.905e, and 558.258 of this chapter.

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

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

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

§ 558.195 [Amended]

42. Amend § 558.195 as follows:

a. In the table in paragraph (e)(1)(i), in the "Limitations" column, remove "Do not feed to laying chickens." and in its place add "Do not feed to laying hens producing eggs for human consumption.";

b. In the table in paragraph (e)(2)(i), in the "Limitations" column, remove "Do not feed to cows producing milk for food." and in its place add "Do not feed to cows producing milk for human consumption.";

c. In the table in paragraphs (e)(3)(i)1. and (e)(3)(ii)1., in the "Limitations" column, remove "Do not feed to sheep producing milk for food." and in its place add "Do not feed to sheep producing milk for human consumption."; and

d. In the table in paragraphs (e)(3)(i)2. and (e)(3)(ii)2., in the "Limitations" column, remove "Do not feed to goats producing milk for food." and in its place add "Do not feed to goats producing milk for human consumption."

43. In § 558.340, redesignate paragraphs (c)(1)(i) and (ii) as paragraphs (c)(2) and (3); and revise newly redesignated paragraph (c)(2) to read as follows:

§ 558.340 Maduramicin.

* * * * *

(c) * * *

(2) Indications for use. Broiler chickens: For prevention of coccidiosis caused by Eimeria acervulina, E. tenella, E. brunetti, E. maxima, E. necatrix, and E. mivati.

* * * * *

44. In § 558.355, revise paragraph (f)(1)(xxiv); and revise paragraph (f)(1)(xxv) introductory text and remove and reserve paragraphs (f)(1)(xxx), (f)(4)(iv), and (f)(4)(v).

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxiv) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin methylenedisalicylate, 4 to 50 grams.

(a) Indications for use. For improved feed efficiency; as an aid in the prevention of coccidiosis caused by Eimeria necatrix, E. tenella, E. acervulina, E. maxima, E. brunetti, and E. mivati.

(b) Limitations. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.

(xxv) Amount per ton. Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams.

* * * * *

§ 558.515 [Amended]

45. In § 558.515, in the table in paragraph (d), in the entry for "30 (0.0033 pct)", in the first entry under the "Indications for use" column, remove "For broiler and fryer chickens:" and in its place add "Broiler chickens:"; and in the first entry under the "Limitations" column, remove "Do not feed to layers." and in its place add "Do not feed to chickens producing eggs for food."

§ 558.550 [Amended]

46. Amend § 558.550 as follows:

a. In paragraph (b)(1), remove "054771" and in its place add "016592";

b. Remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2);

c. In paragraph (d)(1)(xvi)(c), remove "Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by Nos. 054771 and 016592 in § 510.600(c) of this chapter." and in its place add "Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.";

d. In paragraph (d)(1)(xx)(C) and (xxi)(C), remove "Salinomycin as provided by 054771; bacitracin methylene disalicylate as provided by 054771 in §510.600(c) in this chapter." and in its place add "Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.";

e. In paragraph (d)(1)(xxii)(B), remove "Salinomycin as provided by Nos. 016592 and 054771; tylosin phosphate as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter." and in its place add "Salinomycin as provided by No. 016592; tylosin phosphate as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.";

f. In paragraph (d)(1)(xxiii)(b), remove "Salinomycin as provided by Nos. 054771 and 016592; bambermycins by No. 016592 in § 510.600(c) of this chapter." and in its place add "Salinomycin and bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.";

g. In paragraphs (d)(3)(ii)(B), (iii)(B), and (v)(B), remove "Salinomycin as provided by 054771; bacitracin methylene disalicylate as provided by 054771 in § 510.600(c) of this chapter." and in its place add "Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter."; and

h. In paragraph (d)(4)(i)(b), remove "Salinomycin as provided by Nos. 054771 and 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter." and in its place add "Salinomycin as provided by No. 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter."

§ 558.586 [Amended]

47. In § 558.586, in paragraph (b), remove "000859" and in its place add "016592".

Dated: April 12, 2016.

Tracey Forfa,

Acting Director,

Center for Veterinary Medicine.

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