We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents our current thinking on nutrition labeling of standard menu items in restaurants and similar retail food establishments. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This SECG refers to collections of information described in FDA's final rule that published in the **Federal Register** of December 1, 2014 (79 FR 71156), and that will be effective on December 1, 2015. As stated in the final rule, these collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). In compliance with the PRA (44 U.S.C. 3507(d)), the Agency has submitted the information collection provisions of the final rule to OMB for review. FDA will publish a document in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

III. Comments

Interested persons may submit either electronic comments regarding the SECG to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the SECG at either *http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: March 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05590 Filed 3–12–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 556, and 558

[Docket No. FDA–2014–N–0002]

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

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 approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during November and December 2014. 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 change of sponsorship of eight NADAs and nine ANADAs, and to make correcting amendments for a drug labeler code.

DATES: This rule is effective March 13, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during November and December 2014, 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.*

In addition, Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144, has transferred ownership of, and all rights and interest in, the following approved applications to Pharmgate LLC, 161 North Franklin Turnpike, Suite 2C, Ramsey, NJ 07446:

File No.	Product name	21 CFR Cite
065–480	Chlortetracycline Soluble Powder	520.441.
138–934	PENNCHLOR SP (chlortetracycline, sulfamethazine, penicillin) Type A medicated articles	558.145.
138–935	PENNCHLOR (chlortetracycline) Type A medicated articles	558.128.
138–938	PENNOX (oxytetracycline) Type A medicated articles	558.450.
138–939	NEO–OXY (neomycin sulfate and oxytetracycline) Type A medicated articles	558.455.
140–680	TYLAN (tylosin phosphate) Type A medicated articles	558.625.
140–681	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine) Type A medicated articles	558.630.
141–137	PENITRACIN (bacitracin methylenedisalicylate) 50 Type A medicated article	Not codified.
200–026	PENNOX 343 (oxytetracycline)	520.1660d.
200–154	PENNOX 200 (oxytetracycline)	558.450.
200–295	PENNCHLOR 64 (chlortetracycline)	558.128.
200–314	PENNCHLOR S (chlortetracycline)	558.140.
200–354	PENNCHLOR (chlortetracycline)/COBAN (monensin)	558.355.
200–356	PENNCHLOR (chlortetracycline)/DENAGARD (tiamulin)	558.600.

File No.	Product name	21 CFR Cite
200–357	PENNCHLOR (chlortetracycline)/BIO–COX (salinomycin)	558.550.
200–358	PENNCHLOR (chlortetracycline)/BMD (bacitracin MD)	558.76.
200–359	PENNCHLOR (chlortetracycline)/DECCOX (decoquinate)	558.195.

At this time, the regulations are being amended to reflect these changes of sponsorship. Following these changes of sponsorship, Pharmgate LLC will now be the sponsor of an approved application while Pennfield Oil Co. will no longer be the sponsor of an approved application. Also, Hikma Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118, has informed FDA that it has changed its name to Hikma International Pharmaceuticals LLC. Accordingly, § 510.600 (21 CFR 510.600) is being amended to reflect these changes. In addition, FDA is amending § 510.600 and several sections of part 520 to reflect a correct drug labeler code for Akorn Animal Health, Inc. FDA is also amending the regulations in 21 CFR parts 520, 522, 556, and 558 to redesignate several sections to reflect alphabetical order and to make minor technical amendments. These corrections and technical amendments are being made to improve the accuracy of the animal drug regulations.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING NOVEMBER AND DECEMBER 2014

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Sections	FOIA Summary	NEPA Review
200–575	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101.	Carprofen Chewable Tablets.	Original approval as a generic copy of NADA 141–111.	520.309	yes	CE[1,2]
141–232	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPLICEF (cefpodoxime proxetil) Chewable Tablets.	Supplemental approval of chewable tablet dosage form for dogs.	520.370	yes	CE[1,3]
200–512	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	TRIAMULOX (tiamulin hydrogen fumarate) Liquid Concentrate.	Original approval as a generic copy of NADA 140–916.	520.2455	yes	CE[1,2]
200–573	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101.	Dexmedetomidine HCl (dexmedetomidine hydrochloride). Injectable Solution	Original approval as a generic copy of NADA 141–267.	522.558	yes	CE[1,2]
141–068	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	BAYTRIL 100 (enrofloxacin). Injectable Solution	Supplemental approval adding administration by intramuscular injection in swine and an indication for control of colibacillosis in groups or pens of weaned pigs.	522.812	yes	CE[1,4]
141–349	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	DRAXXIN 25 ..... (tulathromycin) ..... Injectable Solution	Supplemental approval for treatment of bovine respiratory disease (BRD) in suckling calves, dairy calves, and veal calves.	522.2630	yes	CE[1,4]
141–437	Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408.	OSURNIA ..... (florfenicol, terbinafine, betamethasone acetate) Otic Gel.	Original approval for the treatment of otitis externa in dogs.	524.955	yes	CE[1,3]
034–267	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	GENTOCIN DURAFILM. (gentamicin sulfate and betamethasone). Ophthalmic Solution	Supplemental approval of additional safety information.	524.1044i	yes	CE[1,3]
141–034	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	GAINPRO ..... (bambermycins) ..... Type A medicated article.	Supplemental approval of a free-choice Type C medicated loose mineral feed without selenium for pasture cattle.	558.95	yes	CE[1,2]
200–510[5] ..	Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446.	DERACIN ..... (chlortetracycline) ..... Type A medicated articles.	Original approval as a generic copy of NADA 048–761.	558.128	yes	CE[1,2]
141–258	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	ZILMAX (zilpaterol hydrochloride) Type A medicated article.	Supplemental approval to provide for component feeding of Type C medicated feeds.	558.665	yes	CE[1,2]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING NOVEMBER AND DECEMBER 2014—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Sections	FOIA Summary	NEPA Review
141–276 [5] ..	Intervet, Inc., 556 Morris Ave., Summit, NJ 07901.	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) plus TYLAN (tylosin phosphate) Type C medicated feeds.	Supplemental approval to provide for component feeding of combination drug Type C medicated feeds.	558.665	yes	CE [1 6]

[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(a)(1).
[3] CE granted under 21 CFR 25.33(d)(1).
[4] CE granted under 21 CFR 25.33(d)(5).
[5] This application is affected by guidance for industry (GFI) #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013.
[6] CE granted under 21 CFR 25.33(a)(2).

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 Part 510

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

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 510, 520, 522, 524, 556, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. Amend § 510.600 as follows:

■ a. In the table in paragraph (c)(1), in the entry for ''Akorn Animal Health, Inc.'', in the ''Drug labeler code'' column, remove ''053599'', and in its place add ''059399'';

■ b. In the table in paragraph (c)(1), in the entry for ''Hikma Pharmaceuticals LLC'', in the ''Firm name and address'' column, remove ''Hikma Pharmaceuticals LLC'', and in its place add ''Hikma International Pharmaceuticals LLC'';

■ c. In the table in paragraph (c)(1), remove the entry for ''Pennfield Oil Co.'' and add an entry, in alphabetical order, for ''Pharmgate LLC'';

■ d. In the table in paragraph (c)(2), remove the entries for ''000008'', ''048164'', and ''053599'' and add entries, in numerical order, for ''059399'' and ''069254''; and

■ e. In the table in paragraph (c)(2), in the entry for ''059115'', in the ''Firm name and address'' column, remove ''Hikma Pharmaceuticals LLC'', and in its place add ''Hikma International Pharmaceuticals LLC''.

The additions and revisions read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446	069254
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
059399	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045
* * * * * * *	
069254	Pharmgate LLC, 161 North Franklin Turnpike, suite 2C, Ramsey, NJ 07446

Drug labeler code	Firm name and address
*	* * * * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§§ 520.310 and 520.312 [Redesignated as §§ 520.301 and 520.302]

■ 4. Redesignate §§ 520.310 and 520.312 as §§ 520.301 and 520.302, respectively.

§ 520.309 [Redesignated as § 520.304 and Amended]

■ 5. Redesignate § 520.309 as § 520.304 and revise newly redesignated § 520.304 by adding paragraph (b)(3) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(3) No. 026637 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

* * * * *

■ 6. In § 520.370, revise paragraphs (a) and (b) and in paragraph (c)(2), remove ''*intermedius*'' and in its place add ''*pseudintermedius*'' to read as follows:

§ 520.370 Cefpodoxime tablets.

(a) *Specifications.* (1) Each tablet contains cefpodoxime proxetil equivalent to 100 or 200 milligrams (mg) cefpodoxime.

(2) Each chewable tablet contains cefpodoxime proxetil equivalent to 100 or 200 mg cefpodoxime.

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

(1) No. 026637 for use of product in paragraph (a)(1) of this section as in paragraph (c) of this section.

(2) No. 054771 for use of products in paragraph (a) of this section as in paragraph (c) of this section.

* * * * *

§ 520.441 [Amended]

■ 7. In § 520.441, in paragraph (b)(1), remove ''048164'' and in its place add ''069254''.

■ 8. Amend § 520.1660d as follows:

■ a. In paragraph (b)(6), remove ''048164'' and in its place add ''069254''.

■ b. In paragraphs (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), and (d)(1)(ii)(C)(*3*), revise the last sentence.

The revisions read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by Nos. 054771, 057561, 061133, and 069254.

(B) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by Nos. 054771, 057561, 061133, and 069254.

(C) * * *

(*3*) * * * Zero-day withdrawal for those products sponsored by Nos. 054771, 057561, 061133, and 069254.

* * * * *

■ 9. In § 520.2455, revise paragraphs (b)(3) and (c) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(3) No. 054771 for the product described in paragraph (a)(3) of this section.

(c) *Related tolerances.* See § 556.732 of this chapter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.246 [Amended]

■ 11. In § 522.246, in paragraph (b)(3), remove ''053599'' and in its place add ''059399''.

■ 12. In § 522.558, revise paragraphs (a) and (b) to read as follows:

§ 522.558 Dexmedetomidine.

(a) *Specifications.* Each milliliter of solution contains:

(1) 0.1 milligrams (mg) dexmedetomidine hydrochloride; or

(2) 0.5 mg dexmedetomidine hydrochloride.

(b) *Sponsors.* See sponsors in in § 510.600(c) of this chapter for use as in paragraph (c) of this section:

(1) No. 026637 for use of product described in paragraph (a)(2) of this section;

(2) No. 052483 for use of products described in paragraph (a) of this section.

* * * * *

■ 13. Amend § 522.812 as follows:

■ a. Revise paragraph (b)(2);

■ b. Remove paragraph (e)(3)(i);

■ c. Redesignate paragraphs (e)(3)(ii) and (e)(3)(iii) as paragraphs (e)(3)(i) and (e)(3)(ii), respectively; and

■ d. Revise newly redesignated paragraph (e)(3)(i).

The revisions read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(2) No. 055529 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section, and use of product described in paragraph (a)(2) of this section as in paragraphs (e)(2)(i)(B), (e)(2)(ii)(B), (e)(2)(iii), (e)(3)(i)(B), and (e)(3)(ii) of this section.

* * * * *

(e) * * *

(3) * * *

(i) *Amounts and indications for use.* (A) Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis, Streptococcus suis, Bordetella bronchiseptica,* and *Mycoplasma hyopneumoniae.*

(B) Administer, by subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the treatment and control of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae, Pasteurella multocida, Haemophilus parasuis,* and *Streptococcus suis.*

(C) Administer, either by intramuscular or subcutaneous (behind the ear) injection, a single dose of 7.5 mg/kg of body weight for the control of colibacillosis in groups or pens of weaned pigs where colibacillosis associated with *Escherichia coli* has been diagnosed.

* * * * *

■ 14. In § 522.1222, revise paragraph (b) to read as follows:

§ 522.1222 Ketamine.

* * * * *

(b) *Sponsors.* See Nos. 000859, 026637, 054628, 054771, 059399, and 063286 in § 510.600(c) of this chapter.

* * * * *

§ 522.2474 [Amended]

■ 15. In § 522.2474, in paragraph (b), remove ''053599'' and in its place add ''059399''.

■ 16. In § 522.2630, revise paragraphs (b)(1), (b)(2), (d)(1)(ii)(A), (d)(1)(ii)(B), and (d)(1)(iii) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(1) Product described as in paragraph (a)(1) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Product described as in paragraph (a)(2) of this section for use as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

(d) * * *

(1) * * *

(ii) * * *

(A) *Beef and non-lactating dairy cattle.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis.* For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica, P. multocida, H. somni,* and *M. bovis.* For the treatment of infectious bovine keratoconjunctivitis (IBK) associated with *Moraxella bovis.* For the treatment of bovine foot rot (interdigital necrobacillosis) associated with *Fusobacterium necrophorum* and *Porphyromonas levii.*

(B) *Suckling calves, dairy calves, and veal calves.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis.*

(iii) *Limitations.* (A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. Do not use in female dairy cattle 20 months of age or older. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(B) Calves intended for human consumption must not be slaughtered within 22 days from the last treatment. Not for use in ruminating cattle. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

§ 522.2662 [Amended]

■ 17. In § 522.2662, in paragraph (b)(4), remove ''053599'' and in its place add ''059399''.

§ 522.2670 [Amended]

■ 18. In § 522.2670, in paragraph (b)(1), remove ''053599'' and in its place add ''059399''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 20. Add § 524.955 to read as follows:

§ 524.955 Florfenicol, terbinafine, and betamethasone acetate otic gel.

(a) *Specifications.* Each milliliter of gel contains 10 milligrams (mg) florfenicol, 10 mg terbinafine, and 1 mg betamethasone acetate.

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

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dose (1 tube) per affected ear(s) and repeat administration in 7 days.

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

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

■ 21. In § 524.1044i, revise paragraph (c)(2) to read as follows:

§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

* * * * *

(c) * * *

(2) *Indications for use.* For treatment of external eye infections and inflammation.

* * * * *

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

■ 22. The authority citation for 21 CFR part 556 continues to read as follows:

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

§ 556.738 [Redesignated as § 556.732]

■ 23. Redesignate § 556.738 as § 556.732.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.76 [Amended]

■ 25. In § 558.76, in paragraph (d)(1)(iv), in the ''Limitations'' and ''Sponsor'' columns, remove ''048164'' and in its place add ''069254''.

■ 26. In § 558.95, add paragraph (d)(4)(v) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(4) * * *

(v) Used as a free-choice Type C medicated loose mineral feed for pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) as follows:

(A) *Specifications.*

Ingredient	International feed No.	Percent
Deflorinated phosphate (20.5% calcium, 18.5% phosphorus)	6–01–080	42.50
Sodium chloride (salt)	6–04–152	20.10
Calcium carbonate (38% calcium)	6–01–069	15.45
Corn distillers dried grains w/solubles	5–28–236	9.57
Magnesium oxide	6–02–756	5.15
Vitamin and trace mineral premix *	.....	3.72
Mineral oil	.....	1.00
Yeast (primary dehydrated yeast)	7–05–533	0.75
Bambermycins Type A article (10 g/lb)	.....	0.60
Iron oxide	6–02–431	0.50
Magnesium sulfate (67%)	6–02–758	0.32
Copper sulfate	6–01–720	0.18

Ingredient	International feed No.	Percent
Potassium sulfate (0.33%)	6–06–098	0.16

* Content of vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

(B) *Amount per ton.* 120 grams.

(C) *Indications for use.* For increased rate of weight gain.

(D) *Limitations.* For free-choice feeding to pasture cattle (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers). Feed a non-medicated commercial mineral product for 6 weeks to stabilize consumption between 2.66 and 10.66 ounces per head per day. Feed continuously to provide 10 to 40 milligrams bambermycins per head per day. Daily bambermycins intakes in excess of 20 mg/head/day have not been shown to be more effective than 20 mg/head/day.

* * * * *

■ 27. Amend § 558.128 as follows:

■ a. In paragraph (b)(1), remove ''Nos. 054771, 048164, and 066104'' and in its place add ''Nos. 054771, 066104, and 069254'';

■ b. In paragraphs (e)(4)(ii) and (iv), in the ''Limitations'' column, remove ''048164'' wherever it occurs and in its place add ''069254'';

■ c. In paragraphs (e)(1)(i), (ii), and (iii), (e)(2)(i), (ii), (iii), and (iv), (e)(3)(i), (ii), (iii), and (iv), (e)(4)(i), (ii), (iv), (vii), and (viii), and (e)(5)(i) and (ii), in the ''Sponsor'' column, remove ''048164'' wherever it occurs and in its place in numerical order add ''069254''; and

■ d. Revise paragraphs (e)(1)(iv), (e)(4)(v), and (e)(4)(ix).

The revisions read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(1) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	054771, 069254.
		2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.	012286, 054771, 066104, 069254.

* * * * * (4) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(v) 500 to 4,000 g/ton	Calves, beef and nonlactating dairy cattle; treatment of bacterial enteritis caused by *E. coli* and bacterial pneumonia caused by *P. multocida* susceptible to chlortetracycline.	Feed continuously for not more than 5 days to provide 10 mg/lb body weight per day. To sponsor No. 054771 under NADA 046–699: 24-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal time.	054771 069254
*	*	*	*
(ix) 350 mg/head/day	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: Zero withdrawal time.	012286, 054771, 066104, 069254.
	2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 046–699: 48-h withdrawal time. To sponsor No. 054771 under NADA 048–761 and No. 069254 under ANADA 200–510: zero withdrawal time.	012286, 054771, 066104, 069254.

* * * * *

§ 558.140 [Amended]

■ 28. In § 558.140, in paragraph (b)(1), remove ''048164'' and in its place add ''069254''.

§ 558.145 [Amended]

■ 29. In § 558.145, in paragraph (a)(2), remove ''048164'' and in its place add ''069254''.

§ 558.195 [Amended]

■ 30. In § 558.195, in paragraph (e)(2)(iv), in the ''Limitations'' and ''Sponsor'' columns, remove ''048164'' and in its place add ''069254''.

§ 558.355 [Amended]

■ 31. In § 558.355, in paragraph (f)(1)(xiv)(*b*), remove ''048164'' and in its place add ''069254''.

§ 558.450 [Amended]

■ 32. Amend § 558.450 as follows:
■ a. In paragraph (a)(2), remove ''048164'' and in its place add ''069254'';
■ b. In paragraphs (d)(2)(iii), (d)(2)(iv), and (d)(4)(ii), in the ''Limitations'' column, remove ''048164'' wherever it occurs and in its place add ''069254''; and
■ c. In paragraphs (d)(1)(i), (ii), (iii), and (iv), (d)(2)(i), (ii), (iii), and (iv), (d)(3)(i) and (ii), (d)(4)(i), (ii), (iii), (iv), and (v), and (d)(5)(i), (ii), and (iii), in the ''Sponsor'' column, remove ''048164'' and in its place add ''069254''.

§ 558.455 [Amended]

■ 33. Amend § 558.455 as follows:
■ a. In paragraph (b), remove ''Nos. 048164 and 066104'' and in its place add ''Nos. 066104 and 069254''; and
■ b. In paragraphs (e)(1)(i), (ii), (iii), and (iv), (e)(2)(i), (ii), (iii), and (iv), (e)(3)(i) and (ii), and (e)(4)(i), (ii), (iii), (iv), (v), and (vi), in the ''Sponsor'' column, remove ''048164'' and in its place in numerical order add ''069254''.

§ 558.550 [Amended]

■ 34. In § 558.550, in paragraphs (b)(3) and (d)(1)(xvi)(*c*), remove ''048164'' and in its place add ''069254''.

§ 558.600 [Redesignated as § 558.612 and Amended]

■ 35. Redesignate § 558.600 as § 558.612 and amend newly redesignated § 558.612 as follows:
■ a. In paragraph (c), remove ''§ 556.738'' and in its place add ''§ 556.732''; and
■ b. In paragraph (e)(1)(iii), in the ''Limitations'' and ''Sponsor'' columns, remove ''048164'' and in its place in numerical order add ''069254''.

§ 558.615 [Redesignated as § 558.600]

■ 36. Redesignate § 558.615 as § 558.600.

§ 558.625 [Amended]

■ 37. In § 558.625, in paragraph (b)(5), remove ''048164'' and in its place add ''069254''.

§ 558.630 [Amended]

■ 38. In § 558.630, in paragraph (b)(2), remove ''No. 054771'' and in its place add ''Nos. 054771 and 069254''.

■ 39. Amend § 558.665 as follows:
■ a. Revise paragraphs (d)(1) and (e)(1);
■ b. Redesignate paragraph (d)(2) as paragraph (d)(4); and
■ c. Add paragraphs (d)(2), (d)(3), (e)(7), and (e)(8).

The revisions and additions read as follows:

§ 558.665 Zilpaterol.

* * * * *

(d) * * *

(1) Labeling shall bear the following caution statements: ''Zilpaterol hydrochloride is not for use in animals intended for breeding. Do not allow horses or other equines access to feed containing zilpaterol. Do not use in veal calves.''

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

(3) Labeling of complete Type C medicated feeds shall bear the following caution statements: ''Not to be fed to cattle in excess of 90 mg zilpaterol/head/day in complete feed. If pen consumption of complete feed exceeds 26.5 lb/head/day (90 percent dry matter basis), zilpaterol should not be fed in complete feed.''

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination 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/head/day. Withdrawal period: 3 days.	000061
*	*	* * *	*	*
(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 to cattle during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. Withdrawal period: 3 days.	000061
(8) 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 to cattle during the last 20 to 40 days on feed to provide 60 mg zilpaterol hydrochloride per head per day. See paragraphs §§ 558.355(d) and 558.625(c). Monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter. Withdrawal period: 3 days.	000061

Dated: March 9, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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