4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA-2017-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 or we) is amending the animal drug regulations to reflect application-related actions for a new animal drug application (NADA) and abbreviated new animal drug applications (ANADAs) during May and June 2017. FDA is 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 make technical amendments to improve the accuracy of the regulations.

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, 7500 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 a NADA and ANADAs during May and June 2017, 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 Dockets Management Staff (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: https://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: https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During May and June 2017

Approval date	File number	Sponsor	Product name	Species	Effect of the action	Public documents
May 23, 2017	055-099	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	CLAVAMOX (amoxicillin and clavulanate potassium tablets) Chewables	Dogs and cats	Supplemental approval of a chewable tablet form of the approved tablet	FOI Summary
June 21, 2017	141-338	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140	INTERCEPTOR SPECTRUM (milbemycin oxime/praziquantel) Chewable Tablets	Dogs	Supplemental approval for the treatment and control of adult tapeworm (*Dipylidium caninum*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older	FOI Summary
May 25, 2017	200-610	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186	Medetomidine HCl (medetomidine hydrochloride) Injectable Solution	Dogs	Original approval as a generic copy of NADA 140-999	FOI Summary
June 23, 2017	200-618	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137	ZOLETIL (tiletamine HCl and zolazepam HCl) for Injection	Dogs and cats	Original approval as a generic copy of NADA 106-111	FOI Summary

Following the approval of ANADA 200-610, Modern Veterinary Therapeutics, LLC, will now be included in the lists of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

II. Technical Amendments

We are making several technical amendments in 21 CFR part 558, which was amended on December 27, 2016 (81 FR 94991), and February 24, 2017 (82 FR 11510), as part of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative. We are also making several technical amendments to the regulations for dosage form drugs to reflect revised labeling. These actions are being taken to improve the accuracy of the regulations.

III. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(i)), which requires *Federal Register* publication of "notice[s]…effective as a regulation," of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated 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." Therefore, it 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, which defines a rule as "an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency."

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, in the table in paragraph (c)(1), alphabetically add an entry for "Modern Veterinary Therapeutics, LLC"; and in the table in paragraph (c)(2), numerically add an entry for "015914." The additions 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
* * * * * * *	
Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186	015914
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
015914	Modern Veterinary Therapeutics, LLC, 14343 SW 119th Ave., Miami, FL 33186
* * * * * * *	

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 § 520.88g, revise the section heading and paragraphs (a) and (b) to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

(a) *Specifications*. Each tablet or chewable tablet contains amoxicillin trihydrate and clavulanate potassium equivalent to 50 milligrams (mg) of amoxicillin and 12.5 mg clavulanic acid, 100 mg of amoxicillin and 25 mg clavulanic acid, 200 mg amoxicillin and 50 mg clavulanic acid, or 300 mg amoxicillin and 75 mg clavulanic acid.

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

(1) No. 054771 for use of tablets and chewable tablets as in paragraph (c) of this section.

(2) No. 026637 for use of tablets as in paragraph (c) of this section.

* * * * *

5. In § 520.1445, revise paragraph (c)(1)(ii) to read as follows:

§ 520.1445 Milbemycin oxime and praziquantel.

* * * * *

(c) * * *

(1) * * *

(ii) *Indications for use*. For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of adult roundworm (*Toxocara canis, Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis, Echinococcus multilocularis, E. granulosus,* and *Dipylidium caninum*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

* * * * *

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

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

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

§ 522.1335 [Amended]

7. In § 522.1335, in paragraph (b), remove "052483" and in its place add "Nos. 015914 and 052483".

8. In § 522.2470, revise paragraphs (b), (c)(1)(i) and (ii), and (c)(2) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

(b) *Sponsors*. See Nos. 026637, 051311, and 054771 in § 510.600(c) of this chapter.

(c) * * *

(1) * * *

(i) *Healthy dogs*. An initial intramuscular dosage of 3 to 4.5 milligrams per pound (mg/lb) of body weight for diagnostic purposes; 4.5 to 6 mg/lb of body weight for minor

procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg/lb of body weight. The maximum total safe dose is 13.6 mg/lb of body weight.

(ii) *Healthy cats*. An initial intramuscular dosage of 4.4 to 5.4 mg/lb of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg/lb of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose, and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb of body weight.

(2) *Indications for use*. For restraint or for anesthesia combined with muscle relaxation in cats and in dogs for restraint and minor procedures of short duration (30 minutes average) requiring mild to moderate analgesia.

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

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

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

§ 524.1580a [Amended]

10. In **§** 524.1580a, in paragraph (d)(3), in the second sentence, remove "in" and in its place add "on".

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

12. Amend 529.1030 as follows:

a. Revise paragraph (d)(1)(ii);

b. In the table in paragraph (d)(2)(i), revise footnote 1;

c. In paragraph (d)(2)(ii), in the table, in the heading of the "Administer in earthen ponds indefinitely (µL/L or ppm)" column, remove "indefinitely" and in its place add "single treatment"; and

d. Revise paragraphs (d)(2)(iii) and (d)(3).

The revisions read as follows:

§ 529.1030 Formalin.

* * * * *

(d) * * *

(1) * * *

(ii) All finfish. For control of external protozoa *Ichthyophthirius* spp., *Chilodonella* spp., *Ichthyobodo* spp., *Ambiphrya* spp., *Epistylis* spp., and *Trichodina* spp., and the monogeneans *Cleidodiscus* spp., *Gyrodactylus* spp., and *Dactylogyrus* spp.

* * * * *

(2) * * *

(i) * * *

[1]Treat for up to 4 hours daily. Treatment may be repeated daily until parasite control is achieved. Use the lower concentration when tanks or raceways are heavily loaded with

phytoplankton or shrimp, to avoid oxygen depletion due to the biological oxygen demand created by decay of dead phytoplankton. Alternatively, a higher concentration might be used if dissolved oxygen is strictly monitored.

* * * * *

(iii) For control of fungi of the family Saprolegniaceae on finfish eggs: eggs of all finfish except Acipenseriformes, 1,000 to 2,000 µL/L (ppm) for 15 minutes; eggs of Acipenseriformes, up to 1,500 µL/L (ppm) for 15 minutes. A preliminary bioassay should be conducted on a small subsample of fish eggs to determine sensitivity before treating an entire group. This is necessary for all species because egg sensitivity can vary with species or strain and the unique conditions at each facility.

(3) *Limitations.* Fish tanks and raceways may be treated daily until parasite control is achieved. Pond treatment may be repeated in 5 to 10 days if needed. However, pond treatments for *Ichthyophthirius* spp. should be made at 2-day intervals until control is achieved. Egg tanks may be treated as often as necessary to prevent growth of fungi. Do not use formalin which has been subjected to temperatures below 40 °F, or allowed to freeze. Treatments in tanks and raceways should never exceed 1 hour for fish or 4 hours for penaeid shrimp (even if they show no sign of distress), nor should it exceed 15 minutes for fish eggs. Do not apply formalin to ponds with water warmer than 27 °C (80 °F), when a heavy bloom of phytoplankton is present, or when the concentration of dissolved oxygen is less than 5 milligrams per liter.

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

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

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

§ 558.58 [Amended]

14. In § 558.58, remove paragraphs (f)(4) and (5).

§ 558.366 [Amended]

15. In § 558.366, remove paragraph (e).

Dated: December 5, 2017.

Leslie Kux.

Associate Commissioner for Policy.

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