# Rules and Regulations

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510, 520, and 524

**[Docket No. FDA–2012–N–0002]**

## New Animal Drugs; Cephalexin; Fentanyl; Milbemycin Oxime and Praziquantel

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**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 June 2012. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

**DATES:** This rule is effective August 9, 2012.

**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, email: *george.haibel@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** FDA's Center for Veterinary Medicine is adopting use of a monthly **Federal Register** document to codify approval actions for new animal drug applications (NADAs) and abbreviated new animal drug application (ANADAs). CVM will no longer publish a separate rule for each action. This approach will allow a more efficient use of available resources.

In this document, FDA is amending the animal drug regulations to reflect the original and supplemental approval actions during June 2012, 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.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JUNE 2012

| NADA/ ANADA | Sponsor | New animal drug product name | Action | 21 CFR section | FOIA summary | NEPA review |
|---|---|---|---|---|---|---|
| 141–326 ... | Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137. | RILEXINE (cephalexin) Chewable Tablets for Dogs. | Original approval for the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius*. | New 520.376 | yes ..... | CE [1] |
| 141–337 ... | Nexcyon Pharmaceuticals, Inc., 644 W. Washington Ave., Madison, WI 53703. | RECUVYRA (fentanyl) Transdermal Solution. | Original approval for control of postoperative pain associated with surgical procedures in dogs. | New 524.916 | yes ..... | CE [1] |
| 141–338 ... | Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408. | INTERCEPTOR SPECTRUM (milbemycin oxime/praziquantel) Chewable Tablets. | Original approval for 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,* and *E. granulosus*) infections in dogs and puppies two pounds of body weight or greater and six weeks of age and older. | New 520.1445 | yes ..... | CE [1] |

[1] The agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment (EA) or an environmental impact statement (EIS) because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

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 and 524*

Animal drugs.

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, and 524 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''Nexcyon Pharmaceuticals, Inc.''; and in the table in paragraph (c)(2), numerically add an entry for ''050929'' to 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 |
|---|---|
| * * * * * | |
| Nexcyon Pharmaceuticals, Inc., 644 W. Washington Ave., Madison, WI 53703 ..... | 050929 |
| * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * * * | |
| 050929 | Nexcyon Pharmaceuticals, Inc., 644 W. Washington Ave., Madison, WI 53703 |
| * * * * * | |

## 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.

■ 4. Section 520.376 is added to read as follows:

**§ 520.376 Cephalexin.**

(a) *Specifications.* Each chewable tablet contains 75, 150, 300, or 600 milligrams (mg) cephalexin.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 22 mg per kilogram of body weight twice daily for 28 days.

(ii) *Indications for use.* For the treatment of secondary superficial bacterial pyoderma in dogs caused by susceptible strains of *Staphylococcus pseudintermedius.*

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

(2) [Reserved]

**§ 520.1445 [Redesignated as § 520.1441]**

**§ 520.1446 [Redesignated as § 520.1443]**

■ 5. Redesignate §§ 520.1445 and 520.1446 as §§ 520.1441 and 520.1443, respectively.

■ 6. Revise the section heading of newly redesignated § 520.1445 to read as follows:

**§ 520.1441 Milbemycin oxime.**

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■ 7. Revise the section heading of newly redesignated § 520.1446 to read as follows:

**§ 520.1443 Milbemycin oxime and lufenuron.**

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■ 8. Add new § 520.1445 to read as follows:

**§ 520.1445 Milbemycin oxime and praziquantel.**

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

(1) 2.3 milligrams (mg) milbemycin oxime and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime and 228 mg praziquantel.

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

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally, once a month, a minimum dosage of 0.23 mg per pound (mg/lb) of body weight (0.5 mg per kilogram (mg/kg)) milbemycin oxime and 2.28 mg/lb of body weight (5 mg/kg) praziquantel.

(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,* and *E. granulosus*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

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

(2) [Reserved]

## PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 10. Add § 524.916 to read as follows:

**§ 524.916 Fentanyl.**

(a) *Specifications.* Each milliliter of solution contains 50 milligrams (mg) fentanyl.

(b) *Sponsor.* See No. 050929 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 1.2 mg/lb (2.7 mg/kg) applied topically to the dorsal scapular area 2 to 4 hours prior to surgery.

(ii) *Indications for use.* For the control of postoperative pain associated with surgical procedures in dogs.

(iii) *Limitations.* Fentanyl is a Class II controlled substance. Observe all ''black-box warnings'' on product labeling. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: August 3, 2012.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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**BILLING CODE 4160–01–P**