DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 526, 529, and 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Bambermycins; Clopidol; Ivermectin; Penicillin G Procaine and Dihydrostreptomycin Sulfate; Progesterone; Robenicoxib; Sulfadimethoxine; Change of Sponsor; Change of Sponsor's Address

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 December 2013. 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 an NADA and a change to a sponsor's address.

DATES: This rule is effective February 27, 2014.

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 December 2013, 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 Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.*

In addition, West Agro, Inc., 11100 North Congress Ave., Kansas City, MO 64153 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 055–028 for QUARTERMASTER (penicillin G procaine and dihydrostreptomycin sulfate) Dry Cow Treatment to HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652. Following this change of sponsorship, West Agro, Inc., is no longer a sponsor of an approved NADA, and HQ Specialty Pharma Corp. is now the sponsor of an approved NADA. Also, Putney, Inc., 400 Congress St., Suite 200, Portland, ME 04101 has informed FDA of a change of address to One Monument Sq., Suite 400, Portland, ME 04101. Accordingly, the Agency is amending the regulations to reflect this change of sponsorship and change of sponsor's address.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING DECEMBER 2013

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA summary	NEPA review
141–419	Huvepharma AD, 5th Floor, 3A Nikolay Haytov St., 1113 Sophia, Bulgaria.	COYDEN 25 (clopidol) plus FLAVOMYCIN (bambermycins) Type A medicated articles.	Original approval as an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency in broiler chickens.	558.95, 558.175	Yes	CE.[1 2]
200–523	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.	SULFAMED (sulfadimethoxine) 40% Injectable Solution.	Original approval as a generic copy of NADA 041–245.	522.2220	Yes	CE.[1 3]
200–564	Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640.	Ivermectin Paste 1.87%	Original approval as a generic copy of NADA 134–314.	[4] N/A	Yes	CE.[1 3]
141–200	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	EAZI–BREED CIDR (progesterone intravaginal insert) Cattle Insert.	Supplemental approval for induction of estrous cycles in anestrous lactating dairy cattle.	529.1940	Yes	EA/FONSI.[5]
141–320	Novartis Animal Health US, Inc., 3200 Northline Ave., Suite 300, Greensboro, NC 27408.	ONSIOR (robenacoxib) Tablets.	Supplemental approval lowering age at treatment from 6 months to 4 months.	520.2075	Yes	CE.[1 6]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING DECEMBER 2013—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR Section	FOIA summary	NEPA review
200–341	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	SPARMECTIN–E (ivermectin) Liquid.	Supplemental approval adding pathogens off exclusivity to labeling.	520.1195	Yes	CE.[1 3]

[1] The Agency has determined under § 25.33 (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 because it is of a type that does not individually or cumulatively have a significant effect on the human environment.
[2] CE granted under § 25.33(a)(2).
[3] CE granted under § 25.33(a)(1).
[4] 21 CFR 520.1192 already contains a drug labeler code entry for this sponsor.
[5] The Agency has carefully considered an EA of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).
[6] CE granted under § 25.33(d)(1).

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, 526, 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 and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 526, 529, 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. In § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''HQ Specialty Pharma Corp.'', revise the entry for ''Putney, Inc.'', and remove the entry for ''West Agro, Inc.''; and in the table in paragraph (c)(2), revise the entry for ''026637'', remove the entry for ''033392'', and numerically add an entry for ''042791'' 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
* * * * *	
HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652 ..	042791
* * * * *	
Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101	026637
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
026637	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.
* * * * *	
042791	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.
* * * * *	

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. In § 520.1195, revise paragraphs (b)(1) and (b)(2) to read as follows:

§ 520.1195 Ivermectin liquid.

* * * * *

(b) * * *

(1) Nos. 000859, 050604, 054925, and 058005 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(A), and (e)(1)(iii) of this section.

(2) No. 058829 for use of product described in paragraph (a)(1) of this section as in paragraphs (e)(1)(i), (e)(1)(ii)(B), and (e)(1)(iii) of this section.

* * * * *

§ 520.2075 [Amended]

■ 5. In § 520.2075, in paragraph (c)(2), remove ''at least 6 months of age'' and in its place add ''at least 4 months of age''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 7. In § 522.2220, revise paragraphs (a)(1), (a)(2), and (a)(3)(iii) to read as follows:

§ 522.2220 Sulfadimethoxine.

(a)(1) *Specifications.* Each milliliter of solution contains 400 milligrams (mg) sulfadimethoxine.

(2) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter for conditions of use as in paragraph (a)(3) of this section:

(i) No. 054771 for use as in paragraph (a)(3) of this section.

(ii) Nos. 000859, 057561, and 061623 for conditions of use as in paragraph (a)(3)(iii) of this section.

(3) * * *

(iii) *Cattle*—(*a*) *Amount.* Administer an initial dose of 25 mg per pound of body weight by intravenous injection followed by 12.5 mg per pound of body weight every 24 hours until the animal is asymptomatic for 48 hours.

(*b*) *Indications for use.* For the treatment of bovine respiratory disease complex (shipping fever complex) and bacterial pneumonia associated with *Pasteurella* spp. sensitive to sulfadimethoxine; necrotic pododermatitis (foot rot) and calf diphtheria caused by *Fusobacterium necrophorum* sensitive to sulfadimethoxine.

(*c*) *Limitations.* Milk taken from animals during treatment and for 60 hours (5 milkings) after the latest treatment must not be used for food. Do not administer within 5 days of slaughter. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

* * * * *

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.1696c [Amended]

■ 9. In paragraph (b) of § 526.1696c, remove ''033392'' and in its place add ''042791''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 529 continues to read as follows:

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

■ 11. In § 529.1940, in paragraphs (b) and (e)(1)(iii), remove ''000009'' and in its place add ''054771''; in paragraph (c), remove ''§ 556.540(a)'' and in its place add ''§ 556.540''; and add paragraph (e)(1)(ii)(D) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(e) * * *

(1) * * *

(ii) * * *

(D) For induction of estrous cycles in anestrous lactating dairy cows.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 13. In paragraph (d)(5) of § 558.95, redesignate paragraphs (d)(5)(iii) through (d)(5)(x) as paragraphs (d)(5)(iv) through (d)(5)(xi); and add new paragraph (d)(5)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(iii) Clopidol as in § 558.175.

* * * * *

■ 14. In § 558.175:

■ a. Redesignate paragraph (d)(9) as paragraph (d)(11).

■ b. Redesignate paragraphs (d)(5) through (d)(8) as paragraphs (d)(6) through (d)(9).

■ c. Add new paragraphs (d)(5) and (d)(10).

The additions read as follows:

§ 558.175 Clopidol.

* * * * *

(d) * * *

Clopidol in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(5) 113.5	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age	016592
*	*	*	*	*
(10) 227	Bambermycins 1 to 2	Broiler chickens: As an aid in prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* and for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration until 5 days before slaughter. Withdraw 5 days before slaughter or feed 113.5 g/ton clopidol and 1 to 2 g/ton bambermycins during those 5 days before slaughter. Do not feed to chickens over 16 weeks of age	016592
*	*	*	*	*

Dated: January 27, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–01959 Filed 2–26–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524, 526, and 529

[Docket No. FDA–2014–N–0002]

New Animal Drugs; 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 a change of sponsor for 54 approved new animal drug applications (NADAs) and 1 approved abbreviated new animal drug application (ANADA) for topical, intramammary, and certain other dosage form new animal drug products from Pfizer, Inc., including its several subsidiaries and divisions, to Zoetis, Inc.

DATES: This rule is effective February 27, 2014.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl.,