4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, and 558

[Docket No. FDA-2014-N-0002]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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 September and October 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 six NADAs and four ANADAs, the voluntary withdrawal of approval of an ANADA, and a correcting amendment.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], except for the amendment to 21 CFR 520.1660d, which is effective [INSERT DATE 10 DAYS AFTER 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, 240-276-9019, george.haibel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during September and October 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, Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601, has transferred ownership of, and all rights and interest in, the following approved applications to Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045.

File Number	Product Name	21 CFR Cite
139-236	ANASED (xylazine hydrochloride) Injectable Solution	522.2662
140-866	YOBINE (yohimbine hydrochloride) Injectable Solution	522.2670
140-994	TOLAZINE (tolazine hydrochloride) Injectable Solution	522.2474
200-055	VETAKET (ketamine hydrochloride) Injectable Solution	522.1222
200-332	BUTORPHIC (butorphanol tartrate) Injectable Solution	522.246

Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601, has transferred ownership of, and all rights and interest in, the following approved applications to Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.

File Number	Product Name	21 CFR Cite
141-431	FOLLTROPIN (follicle stimulating hormone) Injection	522.1002
200-266	BUTEQUINE (phenylbutazone) Paste	520.1720c
200-432	NEXHA (hyaluronate sodium) Injection	522.1145

In addition, Veterinary Service, Inc. 4100 Bangs Ave., Modesto, CA 95356, has transferred ownership of, and all rights and interest in, NADA 065-252 for STREP-SOL (streptomycin sulfate) Oral Solution to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria.

Also, Elanco Animal Health, Inc., A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, has transferred ownership of, and all rights and interest in, NADA 141-272 for RECONCILE (fluoxetine hydrochloride) Chewable Tablets to Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53703.

At this time, the regulations are being amended to reflect these changes of sponsorship. Following these changes of sponsorship, Akorn Animal Health, Inc., Nexcyon Pharmaceuticals, Inc., and Vétoquinol USA, Inc. will now be the sponsors of an approved application while Bioniche Animal Health USA, Inc. and Veterinary Service, Inc. will no longer be the sponsors of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to reflect these changes.

FDA is also amending the regulations at 21 CFR 558.76 to remove a limitation on the concentrations of bacitracin methylene disalicyclate Type A medicated articles that can be used to manufacture medicated feed for quail. In addition, FDA is removing reserved 21 CFR 558.105

for which there is no entry. These actions are being taken to improve the accuracy of the regulations.

Also, Vétoquinol N.-A., Inc., 2000 chemin Georges, Lavaltrie (PQ), Canada, J5T 3S5, has requested that FDA withdraw approval of ANADA 200-305 for Oxytetracycline Hydrochloride Soluble Powder because the product is no longer manufactured or marketed. Note this ANADA was identified as being 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.

Elsewhere in this issue of the Federal Register, FDA gave notice that approval of ANADA 200-305, and all supplements and amendments thereto, is withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this voluntary withdrawal of approval.

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.

Table 1.--Original and Supplemental NADAs and ANADAs Approved During September and October 2014

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Sections	FOIA Summary	NEPA Review
141-244	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007	DRAXXIN (tulathromycin) Injectable Solution	Supplemental approval for treatment of bovine respiratory disease (BRD) in suckling calves, dairy calves, and veal calves	522.2630	yes	CE[1,2]
141-430[3]	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	STAFAC (virginiamycin) plus COBAN (monensin) combination drug Type C medicated feeds	Original approval for prevention of coccidiosis and necrotic enteritis in broiler chickens	558.355	yes	CE[1,4]
200-522	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	Carprofen Sterile Injectable Solution	Original approval as a generic copy of NADA 141-199	522.304	yes	CE[1,5]
200-540	Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101	Meloxicam (meloxicam) Solution for Injection	Original approval as a generic copy of NADA 141-219	522.1367	yes	CE[1,5]
200-581	Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland	FLUNAZINE (flunixin meglumine) Equine Paste	Original approval as a generic copy of NADA 137-409	520.970	yes	CE[1,5]

[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)(5).

[3]This application is affected by 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.

[4]CE granted under 21 CFR 25.33(a)(2).

[5]CE granted under 21 CFR 25.33(a)(1).

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520 and 522

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, 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), remove the entries for "Bioniche Animal Health USA, Inc." and "Veterinary Service, Inc." and alphabetically add entries for "Akorn Animal Health, Inc.", "Nexcyon Pharmaceuticals, Inc.", and "Vétoquinol USA, Inc."; and in the table in paragraph (c)(2), remove the entries for "033008" and "064847" and numerically add entries for "017030", "050929", and "053599" 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
* * * * *	
Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045	053599
* * * * *	
Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719	050929
* * * * *	
Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137	017030
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
017030	Vétoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137
* * * * *	
050929	Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719
* * * * *	
053599	Akorn Animal Health, Inc., 1925 West Field Ct., suite 300, Lake Forest, IL 60045
* * * * *	

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 § 520.970, revise paragraphs (b) and (c)(1) to read as follows:

§ 520.970 Flunixin.

* * * * *

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

(1) No. 000061 for use of products described in paragraph (a).

(2) No. 061623 for use of the product described in paragraph (a)(2).

(c) * * *

(1) Amount. 0.5 mg per pound of body weight per day for up to 5 days.

* * * * *

§ 520.980 [Amended]

5. In paragraph (b) of § 520.980, remove "000986" and in its place add "050929".

§ 520.1660d [Amended]

6. In § 520.1660d, remove paragraph (b)(8); and in paragraphs (d)(1)(ii)(A)(3), (d)(1)(ii)(B)(3), (d)(1)(ii)(C)(3), and (d)(1)(iii)(C), remove "059320,".

§ 520.1720c [Amended]

7. In paragraph (b)(2) of § 520.1720c, remove "064847" and in its place add "017030".

§ 520.2158 [Amended]

8. In paragraph (b) of § 520.2158, remove "033008" and in its place add "016592".

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

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

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

§ 522.246 [Amended]

10. In paragraph (b)(3) of § 522.246, remove "061690" and in its place add "053599".

11. In § 522.304, revise paragraph (b) to read as follows:

§ 522.304 Carprofen.

* * * * *

(b) Sponsors. See Nos. 026637, 054771, and 055529 in § 510.600(c) of this chapter.

* * * * *

§ 522.1002 [Amended]

12. In paragraph (c)(2) of § 522.1002, remove "064847" and in its place add "017030".

§ 522.1145 [Amended]

13. In paragraph (e)(2)(ii) of § 522.1145, remove "064847" and in its place add "017030".

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

§ 522.1222 Ketamine.

* * * * *

(b) Sponsors. See Nos. 000859, 026637, 053599, 054628, 054771, and 063286 in § 510.600(c) of this chapter.

* * * * *

15. In § 522.1367, revise paragraph (b) to read as follows:

§ 522.1367 Meloxicam.

* * * * *

(b) Sponsors. See Nos. 000010, 016729, 026637, and 055529 in § 510.600(c) of this chapter.

* * * * *

§ 522.2474 [Amended]

16. In paragraph (b) of § 522.2474, remove "061690" and in its place add "053599".

17. In § 522.2630, revise paragraph (d)(1) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(d) * * *

(1) Cattle--(i) Amount. 2.5 mg per kilogram (/kg) body weight as a single subcutaneous injection in the neck.

(ii) Indications for use--(A) Beef and non-lactating dairy cattle; 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;

(B) Beef and non-lactating dairy cattle: 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 associated with Moraxella bovis. For the treatment of bovine foot rot (interdigital necrobacillosis) associated with Fusobacterium necrophorum and Porphyromonas levii.

(iii) Limitations. 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.

* * * * *

§ 522.2662 [Amended]

18. In paragraph (b)(4) of § 522.2662, remove "061690" and in its place add "053599".

19. Revise § 522.2670 to read as follows:

§ 522.2670 Yohimbine.

(a) Specifications. Each milliliter (mL) of solution contains 2 or 5 milligrams (mg) of yohimbine (as hydrochloride).

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

(1) No. 053599 for use of in 2 mg/mL solution as in paragraph (c)(1) of this section.

(2) No. 053923 for use of in 5 mg/mL solution as in paragraph (c)(2) of this section.

(c) Conditions of use--(1) Dogs--(i) Amount. Administer 0.05 mg per pound (0.11 mg per kilogram) of body weight by intravenous injection.

(ii) Indications for use. To reverse the effects of xylazine in dogs.

(iii) Limitations. Not for use in food-producing animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Deer and elk--(i) Amount. Administer 0.2 to 0.3 mg per kilogram of body weight by intravenous injection.

(ii) Indications for use. A s an antagonist to xylazine sedation in free ranging or confined members of the family Cervidae (deer and elk).

(iii) Limitations. Do not use in domestic food-producing animals. Do not use for 30 days before or during hunting season. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

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

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

§ 558.76 [Amended]

21. In § 558.76, in paragraph (d)(1)(x), in the entry for "Quail", in the "Limitations" column, remove the first sentence.

§ 558.105 [Removed]

22. Remove reserved § 558.105.

23. In § 558.355, add paragraph (f)(1)(xxxi) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(1) * * *

(xxxi) Amount per ton. Monensin, 90 to 110 grams; plus virginiamycin, 20 grams.

(a) Indications for use. Broiler chickens: As an aid in the prevention of coccidiosis caused by E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima; and for prevention of necrotic enteritis caused by Clostridium perfringens susceptible to virginiamycin.

(b) Limitations. Feed continuously as sole ration. Do not feed to laying chickens. See paragraph (d) of this section. As monensin provided by No. 000986; virginiamycin as provided by No. 066104 in § 510.600(c) of this chapter.

* * * * *

Dated: December 9, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2014-29249 Filed 12/12/2014 at 8:45 am; Publication Date: 12/15/2014]