DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correcting amendments.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January and February 2017. 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 several changes of sponsorship of applications and to make correcting amendments to improve the accuracy of the regulations.

DATES: This rule is effective May 10, 2017, except for amendatory instruction 3 to 21 CFR 510.600, and amendatory instruction 10 to 21 CFR 522.1002, which are effective May 22, 2017.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 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 NADAs and an ANADA during January and February 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 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.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY AND FEBRUARY 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 13, 2017	141–468	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	STAFAC (virginiamycin) plus BIO–COX (salinomycin) combination drug Type C medicated feeds.	Chickens	Original approval for prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary.
January 13, 2017	141–469	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	STAFAC (virginiamycin) plus AMPROL (amprolium) combination drug Type C medicated feeds.	Chickens	Original approval for prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary.
January 13, 2017	141–470	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	STAFAC (virginiamycin) plus AVATEC (lasalocid) combination drug Type C medicated feeds.	Chickens	Original approval for prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary.
January 13, 2017	141–472	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str.,1113 Sophia, Bulgaria.	STAFAC (virginiamycin) plus CLINACOX (diclazuril) combination drug Type C medicated feeds.	Chickens	Original approval for prevention of necrotic enteritis and coccidiosis in broiler chickens.	FOI Summary.
February 13, 2017	141–445	Intervet, Inc., 2 Giralda Farms,Madison, NJ 07940.	REVALOR–XR (trenbolone acetate and estradiol) Extended-Release Implant.	Cattle	Original approval for increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation in beef steers and heifers fed in confinement for slaughter.	FOI Summary; EA/FONSI.[1]
February 17, 2017	200–609	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.	DIROBAN (melarsomine dihydrochloride) Powder for Injection.	Dogs	Original approval as a generic copy of NADA 141–042.	FOI Summary.

[1] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).

Following the approval of ANADA 200–609, Anzac Animal Health, LLC will now be included in the lists of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

II. Changes of Sponsorship

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201:

File No.	Product name	21 CFR section
141–099	CYDECTIN (moxidectin) Pour-On for Beef and Dairy Cattle	524.1450
141–220	CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle	522.1450
141–247	CYDECTIN (moxidectin) Oral Drench for Sheep	520.1454

Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

File No.	Product name	21 CFR section
141–420	TILDREN (tiludronate disodium) Powder for Infusion	522.2473
200–481	ALTRESYN (altrenogest) Solution 0.22%	520.48

Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France:

File No.	Product name	21 CFR section
200–587	FERROFORTE (gleptoferron) Solution, 200 mg/mL	522.1055

Nexcyon Pharmaceuticals, Inc., P.O. Box 259158, Madison, WI 53725 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514:

File No.	Product name	21 CFR section
141–272	RECONCILE (fluoxetine hydrochloride) Chewable Tablets	520.980

Accordingly, the animal drug regulations are being amended to reflect these changes of sponsorship. Following this withdrawal of approval, Nexcyon Pharmaceuticals, Inc. is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c).

III. Withdrawals of Approval

In addition, during January and February 2017, the following sponsor requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
009–505	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.	F.S.H.-P (follicle stimulating hormone) Powder for Injection.	522.1002

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 009–505, and all supplements and amendments thereto, is withdrawn, effective May 22, 2017. Following this withdrawal of approval, Sioux Biochemical, Inc., is no longer the sponsor of an approved application. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this voluntary withdrawal of approval.

IV. Technical Amendments

We are also making several technical amendments in 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. These actions are being taken to improve the accuracy of the regulations.

This final rule is issued under Section 512(i) of the Federal Food, Drug, and Cosmetic 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 Federal Food, Drug, and Cosmetic 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.'' As such, this document is also not subject to Executive Order 12866.

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 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, 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. Effective May 10, 2017, in § 510.600, in the table in paragraph (c)(1), alphabetically add an entry for ''Anzac Animal Health, LLC'', and remove the entry for ''Nexcyon Pharmaceuticals, Inc.''; and in the table in paragraph (c)(2), remove the entry for ''050929'', and numerically add an entry for ''086073.'' 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
* * * * * * *	
Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043	086073
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086073	Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043.
* * * * * * *	

§ 510.600 [Amended]

■ 3. Effective May 22, 2017, in § 510.600, in the table in paragraph (c)(1), remove the entry for ''Sioux Biochemical, Inc.'' .''; and in the table in paragraph (c)(2), remove the entry for ''063112''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 4. The authority citation for part 520 continues to read as follows:

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

§ 520.48 [Amended]

■ 5. In § 520.48, in paragraph (b), remove ''013744'' and in its place add ''061623''.

§ 520.980 [Amended]

■ 6. In § 520.980, in paragraph (b), remove ''050929'' and in its place add ''055246''.

§ 520.1454 [Amended]

■ 7. In § 520.1454, in paragraph (b), remove ''000010'' and in its place add ''000859''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.90b [Amended]

■ 9. In § 522.90b, in paragraph (a), remove ''50, 100, or 250'' and in its place add ''200, 250, or 400''.

§ 522.1002 [Amended]

■ 10. Effective May 22, 2017, in § 522.1002, remove paragraph (b); and redesignate paragraph (c) as paragraph (b).

§ 522.1055 [Amended]

■ 11. In § 522.1055, in paragraph (b), remove ''Nos. 013744 and 061623'' and in its place add ''No. 013744''.

§ 522.1362 [Amended]

■ 12. In § 522.1362, in paragraph (b), remove ''No. 050604'' and in its place add ''Nos. 050604 and 086073''.

§ 522.1450 [Amended]

■ 13. In § 522.1450, in paragraph (b), remove ''000010'' and in its place add ''000859''.

■ 14. In § 522.1662a, revise paragraph (e)(1); and in paragraph (e)(3)(i)(*c*), revise the fifth sentence to read as follows:

§ 522.1662a Oxytetracycline hydrochloride injection.

* * * * *

(e) * * *

(1) *Specifications.* Each milliliter of solution contains 100 milligrams of oxytetracycline hydrochloride.

* * * * *

(3) * * *

(i) * * *

(*c*) * * * Exceeding the highest recommended dose of 5 milligrams per pound of body weight per day, administering more than the recommended number of treatments, and/or exceeding 10 milliliters intramuscularly or subcutaneously per injection site in adult beef and dairy cattle may result in antibiotic residues beyond the withdrawal period. * * *

* * * * *

§ 522.2473 [Amended]

■ 15. In § 522.2473, in paragraph (b), remove ''013744'' and in its place add ''061623''.

■ 16. In § 522.2477, revise paragraph (b)(2) and add paragraph (d)(4) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(G), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), (d)(3)(iii), and (d)(4) of this section.

* * * * *

(d) * * *

(4) *Beef steers and heifers fed in confinement for slaughter*—(i) *Amount.* Each extended- and delayed-release implant contains 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency during 70 to 200 days after implantation.

(iii) *Limitations.* Implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Do not use in calves to be processed for veal. A withdrawal period has not been established for this product in pre-ruminating calves. Effectiveness and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (beef steers and heifers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1450 [Amended]

■ 18. In § 524.1450, in paragraph (b)(1), remove ''000010'' and in its place add ''000859''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

■ 20. In § 558.4, in paragraph (d), in the Category I table, remove the row entry for ''Penicillin''; and in the Category II table, remove the row entry for ''Sulfamethazine'' the first time it appears only along with the subsequent entries for ''Chlortetracycline'' and ''Penicillin''.

§ 558.76 [Amended]

■ 21. In § 558.76, remove and reserve paragraph (e)(1)(vii).

■ 22. In § 558.115, revise paragraph (d)(4) to read as follows:

§ 558.115 Carbadox.

* * * * *

(d) * * *

(4) Carbadox may also be used in combination with oxytetracycline as in § 558.450.

■ 23. Amend § 558.128 as follows:

■ a. In paragraph (b)(1), remove ''50, 65, or 100'' and in its place add ''50, 90, or 100'';

■ b. In paragraphs (e)(1)(i) and (v), in the ''Limitations'' column, remove ''Do not feed to chickens producing eggs for human consumption.'' and in its place add ''For No. 066104: Do not feed to chickens producing eggs for human consumption.'';

■ c. In paragraph (e)(3)(v), in the ''Sponsor'' column, add ''054771'' before ''069254'';

■ d. In paragraph (e)(4)(iii), in the ''Indications for use'' column, remove ''anaplsmosis'' and in its place add ''anaplasmosis''; and

■ e. Redesignate paragraphs (e)(4)(xxiv) and (xxv) as paragraphs (e)(4)(xxv) and (xxvi), respectively, and add new paragraph (e)(4)(xxiv).

The addition reads as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(xxiv) 25 to 2,800 to provide 350 mg/head/day.	Lasalocid, 30 to 181.8.	Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline; and for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*.	Hand feed continuously at a rate of 350 mg chlortetracycline and 1 mg lasalocid per 2.2 lb. body weight daily to cattle with a maximum of 360 mg of lasalocid per head per day. Do not allow horses or other equines access to feeds containing lasalocid. No withdrawal period is required. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal. See § 558.311(d) of this chapter. Chlortetracycline and lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	* *	* *	*

* * * * *

§ 558.140 [Amended]

■ 24. In § 558.140, in paragraph (b)(1), remove ''(d)(1)'' and in its place add ''(e)(1)''; and in paragraph (b)(2), remove ''(d)(2)'' and in its place add ''(e)(2)''.

■ 25. In § 558.325, redesignate paragraphs (e)(2)(vii) to (xvi) as

paragraphs (e)(2)(viii) to (xvii), respectively, and add new paragraph (e)(2)(vii) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(2) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	*	*	*
(vii) 40	Pyrantel, 800	For the treatment and/or control of swine dysentery; for removal and control of large roundworm (*Ascaris suum*) and nodular worm (*Oesophagostomum* spp.) infections.	Feed as a single therapeutic treatment at a rate of 1 lb of feed per 40 lb of body weight for animals up to 200 lb and 5 lb of feed per head for animals over 200 lb. Not to be fed to swine that weigh more than 250 pounds. Withdraw 24 hours prior to slaughter. See paragraph (d) of this section. Lincomycin as provided by No. 054771; pyrantel as provided by No. 066104 in § 510.600(c) of this chapter.	066104
*	*	*	*	*

■ 26. In § 558.366, revise paragraph (e) to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(e) Nicarbazin may also be used in combination with:

(1)–(3) [Reserved]

(4) Lincomycin as in § 558.325.

§ 558.485 [Amended]

■ 27. In § 558.485, remove paragraph (e)(1)(iv).

■ 28. In § 558.550, add paragraph (d)(5) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(d) * * *

(5) Salinomycin may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Chlortetracycline as in § 558.128.

(iv) Lincomycin as in § 558.325.

■ 29. Amend § 558.625 as follows:

■ a. Revise paragraph (d)(2);

■ b. Add paragraphs (d)(4) and (5);

■ c. In paragraphs (e)(2)(iv), (v), (viii), (x), (xii), and (xiii), in the ''Limitations'' column, add a new sentence ''See § 558.355(d) in this chapter.'' between the fourth and fifth sentences;

■ d. In paragraph (e)(2)(vi), in the ''Limitations'' column, add a new sentence ''See § 558.355(d) in this chapter.'' between the seventh and eighth sentences; and

■ e. In paragraphs (e)(2)(vii), (ix), (xi), (xiv), and (xv), in the ''Limitations'' column, add a new sentence ''See § 558.355(d) in this chapter.'' between the fifth and sixth sentences.

The revisions and additions read as follows:

§ 558.625 Tylosin.

* * * * *

(d) * * *

(2) The expiration date of VFDs for tylosin medicated feeds must not exceed 6 months from the date of issuance. VFDs for tylosin shall not be refilled.

* * * * *

(4) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.

(5) Do not use tylosin liquid Type B medicated feeds in any liquid feed containing sodium metabisulfite or in any finished feed (supplement, concentrate, or complete feed) containing in excess of 2 percent bentonite.

* * * * *

■ 30. In § 558.635, revise paragraph (e)(1) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) *Conditions of use*—(1) *Chickens*—

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(i) 20		Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin.	Not for use in layers	066104
(ii) 20	Amprolium 72.6 to 113.5.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella*.	For field conditions where only *E. tenella* is the major problem, feed continuously as the sole ration. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in § 510.600(c) of this chapter.	066104
(iii) 20	Amprolium 113.5 to 227.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis where immunity to coccidiosis is not desired.	For most field conditions as they exist under modern management practices, feed 113.5 g/ton amprolium continuously. Where severe coccidiosis conditions exist, feed 227 g/ton. Use as the sole source of amprolium. Do not use in feeds containing bentonite. Not for use in laying chickens. Amprolium as provided by No. 016592 in § 510.600(c) of this chapter.	066104

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
(iv) 20	Diclazuril 0.91	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati),* and *E. maxima.* Because diclazuril is effective against *E. maxima* late in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not use in hens producing eggs for human food. Diclazuril as provided by No. 016592 in § 510.600(c) of this chapter.	016592
(v) 20	Lasalocid 68 to 113	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed continuously as the sole ration. Do not feed to laying chickens. For broiler or fryer chickens only. Lasalocid as provided by No. 054771 in § 510.600(c) of this chapter.	066104
(vi) 20	Monensin 90 to 110	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. maxima,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to laying chickens. See § 558.355(d) in this chapter. Monensin as provided by No. 058198 in § 510.600(c) of this chapter.	066104
(vii) 20	Salinomycin 40 to 60	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati*.	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.	.....
(viii) 20	Semduramicin 22.7	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104
(ix) 20	Semduramicin (biomass) 22.7.	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria acervulina, E. brunetti, E. maxima, E mivati/mitis, E. necatrix,* and *E. tenella*.	Feed continuously as the sole ration. Withdraw 1 day before slaughter. Do not feed to laying hens. Semduramicin as provided by No. 066104 in § 510.600(c) of this chapter.	066104

* * * * *

■ 31. In § 558.680, remove paragraph (e) and add paragraph (d)(3) to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) * * *

(3) Zoalene may also be used in combination with:

(i)–(ii) [Reserved]

(iii) Lincomycin as in § 558.325.

Dated: May 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09364 Filed 5–9–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA). This action is being taken at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective May 22, 2017.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250 has requested that FDA withdraw approval of NADA 009–505 for F.S.H.-P (follicle stimulating hormone) Powder for Injection because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 009–505, and all supplements and amendments thereto, is hereby withdrawn, effective May 22, 2017.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of this application.

Dated: May 4, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–09365 Filed 5–9–17; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 15

[Docket No. FR–5986–C–02]

RIN 2501–AD81

Revision of Freedom of Information Act Regulation; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Final rule; correction.

SUMMARY: On January 12, 2017, HUD issued a final rule amending HUD's Freedom of Information Act (FOIA) regulation to implement the FOIA Improvement Act of 2016, which enacted a range of procedural changes, including a change to the procedures for withholding information and an amendment to one of the nine FOIA exemptions that authorizes an agency to withhold various records from disclosure. After publication, HUD discovered that a portion of the regulation was not published as intended. Specifically, the published rule deleted several of the nine statutory FOIA disclosure exemptions and duplicated another. HUD also noticed minor technical changes required elsewhere in its regulations. This document corrects HUD's January 12, 2017, final rule and makes the minor technical changes.

DATES: *Effective:* May 10, 2017.

FOR FURTHER INFORMATION CONTACT: Helen Goff Foster, Chief Administrative Officer, Office of Administration, Department of Housing and Urban Development, 451 7th Street SW., Room 6100, Washington, DC 20410–0500, telephone number 1–202–402–6838 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at telephone number 1–800–877–8339 (this is a toll-free number).

SUPPLEMENTARY INFORMATION: On January 12, 2017 (82 FR 3623), HUD issued a final rule amending HUD's Freedom of Information Act (FOIA) regulation at 24 CFR part 15 to implement the FOIA Improvement Act of 2016 (Pub. L. 114–185, approved June 30, 2016) (2016 Act). Upon review of the published rule, HUD determined that § 15.107 was not published as intended. The amendatory instruction excluded three of the nine statutory FOIA exemptions (5 U.S.C. 552(b)) and included a duplicate exemption in § 15.107(b).

HUD's January 12, 2017, final rule sought to restructure § 15.107 by adding paragraph (a) to provide that HUD shall withhold information only if it is reasonably foreseeable that disclosure would harm an interest protected by an exemption, or if disclosure is prohibited by law. HUD also sought to redesignate the undesignated introductory text as paragraph (b), redesignate paragraphs (a) through (i) as (b)(1) through (b)(9), and amend redesignated paragraph (b)(5), the deliberative process privilege, to add a sunset clause after 25 years.

As discussed above, HUD's final rule did not accurately restructure § 15.107 as intended. This final rule restates in whole § 15.107 to reflect the changes required by the 2016 Act to the deliberative process privilege exemption, and restores all other FOIA disclosure exemptions.

In addition, HUD is fixing an incorrect Web site link in § 15.101, removing two misplaced words in § 15.105, and correcting the number of days a FOIA requester has to appeal an adverse determination in § 15.109(a), consistent with the change HUD made in § 15.105(d)(2)(iv).

List of Subjects in 24 CFR Part 15

Classified information, Courts, Freedom of information, Government employees, Reporting and recordkeeping requirements.

Accordingly, 24 CFR part 15 is corrected by making the following correcting amendments:

PART 15—PUBLIC ACCESS TO HUD RECORDS UNDER THE FREEDOM OF INFORMATION ACT AND TESTIMONY AND PRODUCTION OF INFORMATION BY HUD EMPLOYEES

■ 1. The authority for part 15 continues to read as follows:

Authority: 42 U.S.C. 3535(d), 5 U.S.C. 552.

§ 15.101 [Amended]

■ 2. In § 15.101(b)(2), remove the link ''*http://www/data/gov*'' and add in its place the link ''*http://www.data.gov*''.

§ 15.105 [Amended]

■ 3. In § 15.105, in paragraph (d)(2)(iv) remove the word ''and'' and in paragraph (d)(2)(v) remove the word ''and''.

■ 4. Revise § 15.107 to read as follows:

§ 15.107 Documents generally protected from disclosure.

(a) HUD shall withhold information only if HUD reasonably foresees that disclosure would harm an interest protected by an exemption as provided in paragraph (b) of this section, or disclosure is prohibited by law. HUD will consider whether partial disclosure of information is possible whenever