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 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 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/OfficeofMedicalProductsandProteins/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/AnimalVets/ApprovedAnimalDrugProducts/default.htm.

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:

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

<table>
<thead>
<tr>
<th>Approval date</th>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Species</th>
<th>Effect of the action</th>
<th>Public documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>February 13, 2017 ......</td>
<td>141–445</td>
<td>Intervet, Inc., 2 Giralda Farms,Madison, NJ 07940.</td>
<td>REVALOR–XR (trenbolone acetate and estradiol) Extended-Release Implant.</td>
<td>Cattle ...........</td>
<td>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.</td>
<td>FOI Summary; EA/FONSI.¹</td>
</tr>
</tbody>
</table>

¹The 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).
## 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) Judic peace 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 applicability and future effect, which the agency intends to have the force and

### Table: Technical Amendments

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>21 CFR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>009–505</td>
<td>Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250.</td>
<td>F.S.H.-P (follicle stimulating hormone) Powder for Injection.</td>
<td>522.1002</td>
</tr>
<tr>
<td>141–099</td>
<td>CVM’s 11510), as part of the FDA Center for Veterinary Medicine’s (CVM’s)</td>
<td>CYDECTIN (moxidectin) Pour-On for Beef and Dairy Cattle</td>
<td>524.1450</td>
</tr>
<tr>
<td>141–220</td>
<td>CVM’s 11510), as part of the FDA Center for Veterinary Medicine’s (CVM’s)</td>
<td>CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle</td>
<td>522.1450</td>
</tr>
<tr>
<td>141–247</td>
<td>CVM’s 11510), as part of the FDA Center for Veterinary Medicine’s (CVM’s)</td>
<td>CYDECTIN (moxidectin) Oral Drench for Sheep</td>
<td>520.1454</td>
</tr>
</tbody>
</table>

## 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:

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>21 CFR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>141–272</td>
<td>Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514:</td>
<td>RECONCILE (fluoxetine hydrochloride) Chewable Tablets</td>
<td>520.980</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>21 CFR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>200–481</td>
<td>Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:</td>
<td>ALTRESYN (altrenogest) Solution 0.22%</td>
<td>520.48</td>
</tr>
<tr>
<td>200–587</td>
<td>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 application to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France:</td>
<td>FERROFORTE (gleptoferron) Solution, 200 mg/mL</td>
<td>522.1055</td>
</tr>
</tbody>
</table>

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 applications to Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

<table>
<thead>
<tr>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>21 CFR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>141–220</td>
<td>Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:</td>
<td>CYDECTIN (moxidectin) Injectable Solution for Beef and Nonlactating Dairy Cattle</td>
<td>522.1450</td>
</tr>
<tr>
<td>141–099</td>
<td>Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:</td>
<td>CYDECTIN (moxidectin) Pour-On for Beef and Dairy Cattle</td>
<td>524.1450</td>
</tr>
</tbody>
</table>

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.
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:


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:

<table>
<thead>
<tr>
<th>Firm name and address</th>
<th>Drug labeler code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anzac Animal Health, LLC, 218 Millwell Dr., Suite B, Maryland Heights, MO 63043</td>
<td>086073</td>
</tr>
</tbody>
</table>

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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


§ 522.90b [Amended]

5. In § 522.90b, in paragraph (a), remove “013744” and in its place add “061623”.

§ 522.1002 [Amended]

6. In § 522.1002, in paragraph (a), remove “050604” and in its place add “086073”.

7. In § 522.1362, in paragraph (b), remove “000010” and in its place add “000859”.

§ 522.1450 [Amended]

8. In § 522.1450, in paragraph (b), remove “000010” and in its place add “000859”.

9. 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.

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

9. 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.

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

(2) Storage. Store at room temperature.

(3) 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 “006123”.

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

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *


* * * * *

(d) * * *

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

§ 558.115 Carbadox.

* * * * *

(d) * * *

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

§ 558.1450 [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:


§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

§ 558.1450 [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:


§ 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”.

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<table>
<thead>
<tr>
<th>Chlortetracycline amount</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsor</th>
</tr>
</thead>
<tbody>
<tr>
<td>(xxiv) 25 to 2,800 to provide 350 mg/head/day.</td>
<td>Lasalocid, 30 to 181.8.</td>
<td>Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by <em>Anaplasma marginale</em> susceptible to chlortetracycline; and for the control of coccidiosis caused by <em>Eimeria bovis</em> and <em>E. zuernii</em>.</td>
<td>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. 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.</td>
<td>054771</td>
</tr>
</tbody>
</table>

§ 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.

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

§ 558.1450 [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

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§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) * * *

§ 558.1450 [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:


§ 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”.

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<table>
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<tr>
<th>Chlortetracycline amount</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
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<th>Sponsor</th>
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<tbody>
<tr>
<td>(xxiv) 25 to 2,800 to provide 350 mg/head/day.</td>
<td>Lasalocid, 30 to 181.8.</td>
<td>Beef cattle weighing under 700 pounds: For control of active infection of anaplasmosis caused by <em>Anaplasma marginale</em> susceptible to chlortetracycline; and for the control of coccidiosis caused by <em>Eimeria bovis</em> and <em>E. zuernii</em>.</td>
<td>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. 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.</td>
<td>054771</td>
</tr>
</tbody>
</table>

§ 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 “anaplasmosis” 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) * * *
26. In § 558.366, revise paragraph (e) to read as follows:

§ 558.366 Nicarbazin.

| (d) | * * * * *
|-----|-------------------
| (e) | Nicarbazin may also be used in combination with:
| 1)–(3) | [Reserved]
| (4) | Lincomycin as in § 558.325.

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:

§ 558.625 Tylosin.

| (e) | * * *
|-----|-------------------
| (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 refillable.

(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) | * * *
|-----|-------------------
| (1) | Conditions of use—(1) Chickens—

227. In § 558.635, add paragraphs (e)(2)(vi), (vii), (ix), (xi), (xii), and (xiii), in the “Limitations” column, add a new sentence “See § 558.355(d) in this chapter.” between the fourth and fifth sentences; and

31. In § 558.635, add paragraphs (e)(2)(vii), (ix), (xi), (xii), and (xiii), 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) | * * *
|-----|-------------------
| (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.

(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.

(6) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.
<table>
<thead>
<tr>
<th>Virginiamycin grams/ton</th>
<th>Combination in grams/ton</th>
<th>Indications for use</th>
<th>Limitations</th>
<th>Sponsors</th>
</tr>
</thead>
<tbody>
<tr>
<td>(iv) 20 ..................</td>
<td>Diclazuril 0.91 ..........</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em> (mivati), and <em>E. maxima</em>. Because diclazuril is effective against <em>E. maxima</em> 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 <em>E. maxima</em>.</td>
<td>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.</td>
<td>016592</td>
</tr>
<tr>
<td>(v) 20 ..................</td>
<td>Lasalocid 68 to 113 ..</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. mivati</em>, and <em>E. maxima</em>.</td>
<td>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.</td>
<td>066104</td>
</tr>
<tr>
<td>(vi) 20 ..................</td>
<td>Monensin 90 to 110</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and as an aid in the prevention of coccidiosis caused by <em>Eimeria necatrix</em>, <em>E. tenella</em>, <em>E. acervulina</em>, <em>E. brunetti</em>, <em>E. maxima</em>, and <em>E. mivati</em>.</td>
<td>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.</td>
<td>066104</td>
</tr>
<tr>
<td>(vii) 20 ...................</td>
<td>Salinomycin 40 to 60</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <em>Eimeria tenella</em>, <em>E. necatrix</em>, <em>E. acervulina</em>, <em>E. maxima</em>, <em>E. brunetti</em>, and <em>E. mivati</em>.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>(viii) 20 ..................</td>
<td>Semduramicin 22.7 ..</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <em>Eimeria acervulina</em>, <em>E. brunetti</em>, <em>E. maxima</em>, <em>E. mivati/mivatis</em>, <em>E. necatrix</em>, and <em>E. tenella</em>.</td>
<td>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.</td>
<td>066104</td>
</tr>
<tr>
<td>(ix) 20 ..................</td>
<td>Semduramicin (biomass) 22.7.</td>
<td>Broiler chickens: For prevention of necrotic enteritis caused by <em>Clostridium perfringens</em> susceptible to virginiamycin; and for the prevention of coccidiosis caused by <em>Eimeria acervulina</em>, <em>E. brunetti</em>, <em>E. maxima</em>, <em>E. mivati/mivatis</em>, <em>E. necatrix</em>, and <em>E. tenella</em>.</td>
<td>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.</td>
<td>066104</td>
</tr>
</tbody>
</table>

§558.680 Zaolene. *(i)–(ii) [Reserved]*

(iii) Lincomycin as in §558.325.

* * * * *

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

(d) * * *

(3) Zaolene may also be used in combination with:
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.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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) regulations 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.


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 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).


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:


§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