SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' that appeared in the **Federal Register** of June 10, 2014 (79 FR 33072). The document amended FDA's postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. The document was published with an incorrect RIN number. This document corrects the error.

DATES: *Effective date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993–0002, 301–796–1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2014, in FR Doc. 2014–13480, the following correction is made:

1. On page 33073, in the third column, the RIN number heading is corrected to read ''RIN 0910–AF96''.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21266 Filed 9–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310, 314, 329, and 600

[Docket No. FDA–2008–N–0334]

RIN 0910–AF96

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Corrections

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; corrections.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction'' that appeared in the **Federal Register** of August 14, 2014 (79 FR 47655). The document published without the required RIN number and in the Notice category. This document corrects those errors.

DATES: *Effective Date:* September 8, 2014.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993–0002, 301–796–1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 14, 2014, in FR Doc. 2014–19255, the following correction is made:

1. On page 47655, in the first column, add the heading ''RIN 0910–AF96'' between the Docket No. and the title of the document.

Dated: September 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–21267 Filed 9–5–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 558

[Docket No. FDA–2014–N–0002]

New Animal Drugs; Buprenorphine; Carprofen; Danofloxacin; Follicle Stimulating Hormone; Ractopamine; Salinomycin; Tylosin

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 July 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 add a cross reference to a tolerance.

DATES: This rule is effective September 8, 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 July 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 Center for Veterinary Medicine (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.*

Also, the animal drug regulations are being amended in 21 CFR 522.955 to add a cross reference to a tolerance for an inactive vehicle in an injectable dosage form product. This amendment is being made to improve the accuracy of the regulations.

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 JULY 2014

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR sections	FOIA summary	NEPA review
013–076 [1]	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	TYLAN (tylosin tartrate) Soluble Powder.	Supplemental approval for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.	520.2640	yes	EA/FONSI [2]
141–207	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ADVOCIN (danofloxacin injection) Sterile Injectable Solution.	Supplemental approval for control of bovine respiratory disease (BRD) in beef cattle at high risk of developing BRD associated with *Mannheimia haemolytica* and *Pasteurella multocida*.	522.522	yes	CE [3 4]
141–431	Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601.	FOLLTROPIN (porcine pituitary-derived follicle stimulating hormone for injection).	Original approval for the induction of superovulation in beef and dairy heifers and cows.	522.1002	yes	CE [3 5]
141–434	Abbott Laboratories, North Chicago, IL 60064.	SIMBADOL (buprenorphine injection).	Original approval for control of postoperative pain associated with surgical procedures in cats.	522.230	yes	CE [3 6]
200–520	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	CARPRIEVE (carprofen) Injection.	Original approval as a generic copy of NADA 141–199.	522.304	yes	CE [3 7]
200–559	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	ACTOGAIN 45 (ractopamine HCl) plus RUMENSIN (monensin) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–225.	558.500	yes	CE [3 7]
200–566 [1]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	OPTAFLEXX 45 (ractopamine HCl) plus RUMENSIN (monensin) plus TYLOVET (tylosin phosphate) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–224.	558.500	yes	CE [3 7]
200–567 [1]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	OPTAFLEXX 45 (ractopamine HCl) plus RUMENSIN (monensin) plus TYLOVET (tylosin phosphate) plus MGA (melengestrol acetate) Type B and C medicated feeds.	Original approval as a generic copy of NADA 141–233.	558.500	yes	CE [3 7]
200–569 [1]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLAN (tylosin phosphate) plus SACOX (salinomycin sodium) Type C medicated feeds.	Original approval as a generic copy of NADA 141–198.	558.550	yes	CE [3 7]
200–570 [1]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TYLOVET (tylosin phosphate) plus BIO–COX (salinomycin sodium) Type C medicated feeds.	Original approval as a generic copy of NADA 141–198.	558.550	yes	CE [3 7]

[1] The listed application is 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.

[2] 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).

[3] The Agency has determined under 21 CFR 25.33 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 individually or cumulatively have a significant effect on the human environment.

[4] CE granted under 21 CFR 25.33(d)(5).

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

[6] CE granted under 21 CFR 25.33(d)(1).

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

List of Subjects

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 520, 522, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. In § 520.2640, revise paragraphs (b) and (e)(1) to read as follows:

§ 520.2640 Tylosin.

* * * * *

(b) *Sponsors.* (1) No. 000986 for use as in paragraphs (e)(1), (e)(2)(i), (e)(2)(ii)(A), (e)(2)(iii), (e)(3), and (e)(4) of this section.

(2) No. 016592 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2)(i), (e)(2)(ii)(A), (e)(2)(iii), (e)(3), and (e)(4) of this section.

(3) No. 061623 for use as in paragraphs (e)(1)(i)(A), (e)(1)(ii), (e)(2)(i), (e)(2)(ii)(B), (e)(2)(iii), (e)(3), and (e)(4) of this section.

* * * * *

(e) * * *

(1) *Chickens*—(i) *Amounts and indications for use.*—(A) Administer 2 grams per gallon (528 parts per million (ppm)) for 1 to 5 days as an aid in the treatment of chronic respiratory disease (CRD) associated with *Mycoplasma gallisepticum* in broiler and replacement chickens. For the control of CRD associated with *M. gallisepticum* at time of vaccination or other stress in chickens. For the control of CRD associated with *Mycoplasma synoviae* in broiler chickens. Treated chickens should consume enough medicated drinking water to provide 50 milligrams (mg) tylosin per pound of body weight per day.

(B) Administer 851 to 1,419 mg/gallon (225 to 375 ppm) for 5 days for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.

(ii) *Limitations.* Do not use in layers producing eggs for human consumption. Do not administer within 24 hours of slaughter.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Add § 522.230 to read as follows:

§ 522.230 Buprenorphine.

(a) *Specifications.* Each milliliter of solution contains 1.8 milligrams (mg) buprenorphine.

(b) *Sponsor.* See No. 000044 in § 510.600(c) of this chapter.

(c) *Conditions of use in cats*—(1) *Amount.* Administer 0.24 mg per kilogram (0.11 mg per pound) by subcutaneous injection once daily, for up to 3 days. Administer the first dose approximately 1 hour prior to surgery.

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

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

§ 522.304 [Amended]

■ 5. In § 522.304, paragraph (b), remove ''No. 054771'' and in its place add ''Nos. 054771 and 055529''.

■ 6. In § 522.522, remove paragraph (d)(2); redesignate paragraph (d)(3) as paragraph (d)(2); and revise paragraph (d)(1) to read as follows:

§ 522.522 Danofloxacin.

* * * * *

(d) * * *

(1) *Amount and indications for use.* Administer by subcutaneous injection either:

(i) 6 mg per kilogram (/kg) of body weight, repeated in 48 hours, for the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica* and *Pasteurella multocida;* or

(ii) 8 mg/kg of body weight as a single dose for the treatment of BRD associated with *M. haemolytica* and *P. multocida* and for the control of BRD in beef cattle at high risk of developing BRD associated with *M. haemolytica* and *P. multocida.*

* * * * *

■ 7. In § 522.955, revise paragraph (c) to read as follows:

§ 522.955 Florfenicol.

* * * * *

(c) *Related tolerances.* See §§ 500.1410 and 556.283 of this chapter.

* * * * *

■ 8. In § 522.1002, add paragraph (c) to read as follows:

§ 522.1002 Follicle stimulating hormone.

* * * * *

(c)(1) *Specifications.* Each package contains 2 vials. One vial contains 700 international units (IU) porcine-pituitary derived follicle stimulating hormone (FSH) equivalent to 400 milligrams NIH–FSH–P1, as a dry powder. The other vial contains 20 milliliters (mL) of bacteriostatic sodium chloride injection. When reconstituted, each milliliter of constituted solution contains 35 IU FSH.

(2) *Sponsor.* See No. 064847 in § 510.600(c) of this chapter.

(3) *Conditions of use*—(i) *Dosage.* Administer 2.5 mL (87.5 IU) intramuscularly, twice daily at 12-hour intervals, for 4 consecutive days. In conjunction with the 6th dose, administer an approved prostaglandin product for cattle (cloprostenol sodium or dinoprost tromethamine), using the labeled dosage and administration instructions to cause luteolysis and induce estrus. See § 522.460 for use of cloprostenol sodium or § 522.690 for use of dinoprost tromethamine.

(ii) *Indications for use.* For the induction of superovulation in beef and dairy heifers and cows.

(iii) *Limitations.* 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

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

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

■ 10. In § 558.500, revise paragraphs (e)(2)(ii), (e)(2)(iv), (e)(2)(vii), (e)(2)(ix), (e)(2)(x), (e)(2)(xii), and (e)(2)(xiii), to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	As in paragraph (e)(2)(i) of this section; see paragraph §§ 558.355(d) of this chapter. Ractopamine as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 054771
* *	*	* *	*	*
(iv) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii;* and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*.	As in paragraph (e)(2)(i) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Ractopamine as provided by No. 000986 with tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter; or ractopamine as provided by No. 054771 with tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 016592, 054771
* *	*	* *	*	*
(vii) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	As in paragraph (e)(2)(vi) of this section; see paragraph §§ 558.355(d) of this chapter. Ractopamine as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 054771
* *	*	* *	*	*
(ix) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii;* and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*.	As in paragraph (e)(2)(vi) of this section; see §§ 558.355(d) and 558.625(c) of this chapter. Ractopamine and monensin as provided by No. 000986 with tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter; or ractopamine as provided by No. 054771 with monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 016592, 054771

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(x) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii;* for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes;* and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see paragraphs §§ 558.342(d), 558.355(d) and 558.625(c) of this chapter. Ractopamine, monensin, and tylosin as provided by No. 000986 with melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter; or ractopamine and monensin as provided by No. 000986 with tylosin as provided by Nos. 000986 or 016592 and melengestrol acetate as provided by No. 054771 in § 510.600(c) of this chapter; or ractopamine as provided by No. 054771 with monensin and tylosin as provided by No. 000986 and melengestrol acetate provided by No. 054771 in § 510.600(c) of this chapter.	000986, 016592, 054771
* *	*	* *	*	*
(xii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d). Ractopamine as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter; monensin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 054771
(xiii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus tylosin 8 to 10.	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to *Eimeria bovis* and *E zuernii;* and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*.	Top dress ractopamine in a minimum of 1.0 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See §§ 558.355(d) and 558.625(c). Ractopamine and monensin as provided by No. 000986 with tylosin as provided by Nos. 000986 or 016592 in § 510.600(c) of this chapter; or ractopamine as provided by No. 054771 with monensin and tylosin as provided by No. 000986 in § 510.600(c) of this chapter.	000986, 016592, 054771

* * * * *

■ 11. In § 558.550, revise the last sentence in paragraph (d)(1)(xxii)(B) to read as follows:

§ 558.550 Salinomycin.

* * * * *

(d) * * *

(1) * * *

(xxii) * * *

(B) * * * Salinomycin as provided by Nos. 016592 and 054771; tylosin phosphate as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.

* * * * *

Dated: August 21, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–20325 Filed 9–5–14; 8:45 am]

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