DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 529, 556, and 558

[Docket No. FDA–2021–N–0002]

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

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Final rule; technical 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 October, November, and December 2021. FDA is 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 improve the accuracy of the regulations.

DATES: This rule is effective March 29, 2022.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–5689, *George.Haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during October, November, and December 2021, 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 office of the Dockets Management Staff (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, 240–402–7500. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 1, 2021	200–691	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161.	RAC 45 CATTLE (ractopamine hydrochloride Type A medicated article).	Cattle	Original approval as a generic copy of NADA 141–221.	FOI Summary.
October 20, 2021 ...	200–604	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.	Amoxicillin and Clavulanate Potassium for Oral Suspension.	Dogs and cats	Original approval as a generic copy of NADA 055–101.	FOI Summary.
October 28, 2021 ...	200–588	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	Florfenicol Injection (florfenicol) Injectable Solution.	Cattle	Original approval as a generic copy of NADA 141–063.	FOI Summary.
October 29, 2021 ...	200–628	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	Enrofloxacin 100 (enrofloxacin) Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–068.	FOI Summary.
October 29, 2021 ...	141–348	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SYNOVEX ONE Grower (trenbolone acetate and estradiol benzoate extended-release implants).	Cattle	Supplemental approval adding cattle fed in confinement for slaughter.	FOI Summary.
November 1, 2021 ..	200–711	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	TULAVEN 100 (tulathromycin injection) Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–244.	FOI Summary.
November 3, 2021 ..	200–712	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	TULAVEN 25 (tulathromycin injection) Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–349.	FOI Summary.
November 3, 2021 ..	141–508	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	EXPERIOR (lubabegron) Type A medicated article.	Cattle	Supplemental approval adding tolerances for residues in edible tissues of cattle.	FOI Summary.
November 12, 2021	200–668	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161.	TULISSIN 25 (tulathromycin injection) Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–349.	FOI Summary.
November 15, 2021	200–253	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	PROSTAMATE (dinoprost tromethamine injection) Injectable Solution.	Cattle	Supplemental approval for use with gonadorelin or with progesterone intravaginal inserts.	FOI Summary.
November 15, 2021	200–669	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161.	TULISSIN 100 (tulathromycin injection) Injectable Solution.	Cattle and swine.	Original approval as a generic copy of NADA 141–244.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2021—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
November 22, 2021	200–695	Virbac AH, Inc., P.O. Box 162059, Fort Worth, TX 76161.	TIA 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate.	Swine	Original approval as a generic copy of NADA 140–916.	FOI Summary.
November 24, 2021	200–714	Aurora Pharmaceutical, Inc, 1196 Highway 3 South, Northfield, MN 55057–3009.	BARRIER for Cats (imidacloprid and moxidectin) Topical Solution.	Cats	Original approval as a generic copy of NADA 141–254.	FOI Summary.
December 10, 2021	200–705	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	ZOASHIELD (zoalene) Type A medicated article and BMD (bacitracin methylenedisalicylate) Type A medicated article.	Chickens and turkeys.	Original approval as a generic copy of NADA 141–085.	FOI Summary.
December 21, 2021	141–552	Jaguar Animal Health, 200 Pine St., suite 600, San Francisco, CA 94104.	CANALEVIA–CA1 (crofelemer delayed-release tablets).	Dogs	Conditional approval for treatment of chemotherapy-induced diarrhea.	FOI Summary.
December 23, 2021	141–521	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPARICA TRIO (sarolaner, moxidectin, and pyrantel chewable tablets) Chewable Tablet.	Dogs	Supplemental approval for the prevention of *Borrelia burgdorferi* infection as a direct result of killing *Ixodes scapularis* vector ticks and for the treatment and control of L4 and immature adult *Ancylostoma caninum*.	FOI Summary.

II. Change of Sponsor

Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140 has informed FDA that it has transferred ownership of, and all rights and interest in, the NADAs and ANADAs listed below to Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom:

File No.	Product name
047–955	ROMPUN (xylazine hydrochloride) Injectable (20 mg).
047–956	ROMPUN (xylazine hydrochloride) Injectable (100 mg).
200–322	Butorphanol Tartrate Injection.
200–408	Butorphanol Tartrate Injection.

Thorn Bioscience LLC, 1044 East Chestnut St., Louisville, KY 40204 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–319 for SUCROMATE Equine (deslorelin acetate injection) to Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom.

As provided in the regulatory text, the animal drug regulations are amended to reflect these changes of sponsorship.

III. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations:

- 21 CFR 510.600 is amended to add Jaguar Animal Health and remove Thorn Bioscience LLC from the list of sponsors of approved applications.
- 21 CFR 520.88h is amended to correct indications for use in cats of an oral suspension containing amoxicillin and clavulanate.
- 21 CFR 520.2455 is amended to correct a spelling error in the limitations for use of tiamulin in drinking water of swine.
- 21 CFR 522.230 is amended to add the caution that buprenorphine injectable solution is a Schedule III opioid under the Controlled Substances Act.
- 21 CFR 522.690 is amended to reflect revised indications for use of dinoprost tromethamine injectable solution in mares.
- 21 CFR 522.1940 is amended to reflect the approved classes of cattle and limitations for use of progesterone and estradiol benzoate ear implants.
- 21 CFR 522.2343 is amended to reflect the approved classes of cattle and limitations for use of testosterone propionate and estradiol benzoate ear implants.
- 21 CFR 556.240 is amended to reflect the use of revised food consumption values in establishing permitted concentrations of residues of estradiol and related esters in edible tissues of cattle. The basis for this action is explained in the FOI Summary for supplemental NADA 141–348, approved October 29, 2021. The section is also amended to reflect a cross reference for testosterone propionate and estradiol benzoate implants, recently redesignated as 21 CFR 522.2343.
- 21 CFR 558.254 is amended to reflect the approved conditions of use for famphur in feed.
- 21 CFR 558.355 is amended to reflect use of medicated feeds containing monensin alone or in combination with bacitracin methylenedisalicylate in revised classes of chickens.
- 21 CFR 558.555 is amended to correct a spelling error in the permitted combination use of semduramicin in medicated feed.
- 21 CFR 558.633 is amended to revise expiration dates for use of pelleted or crumbled tylvalosin medicated swine feeds.
- 21 CFR 558.680 is amended to reflect the correct sponsor of an application for use of Type C medicated turkey feeds containing zoalene.

IV. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C 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 FD&C 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.''

List of Subjects

21 CFR Part 510

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

21 CFR Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

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, 21 CFR parts 510, 516, 520, 522, 524, 529, 556, 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. In § 510.600:

■ a. In the table in paragraph (c)(1), add in alphabetical order an entry for ''Jaguar Animal Health'' and remove the entry for ''Thorn Bioscience LLC''; and

■ b. In the table in paragraph (c)(2), remove the entry for ''051330'' and add in numerical order an entry for ''086149''.

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
* * * * * * *	
Jaguar Animal Health, 200 Pine St., Suite 600, San Francisco, CA 94104	086149
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086149	Jaguar Animal Health, 200 Pine St., Suite 600, San Francisco, CA 94104.
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority 21 U.S.C. 360ccc, 360ccc–2, 371.

■ 4. Add § 516.498 to subpart C to read as follows:

§ 516.498 Crofelemer.

(a) *Specifications.* Each delayed-release tablet contains 125 milligrams (mg) crofelemer.

(b) *Sponsor.* See No. 086149 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer 1 tablet orally twice daily for 3 days for dogs weighing ≤140 pounds. Administer 2 tablets orally twice daily for 3 days for dogs weighing >140 pounds.

(2) *Indications for use.* For the treatment of chemotherapy-induced diarrhea in dogs.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 6. Revise § 520.88h to read as follows:

§ 520.88h Amoxicillin trihydrate and clavulanate potassium for oral suspension.

(a) *Specifications.* When constituted, each milliliter (mL) of suspension contains amoxicillin trihydrate equivalent to 50 milligrams (mg) amoxicillin and clavulanate potassium equivalent to 12.5 mg clavulanic acid.

(b) *Sponsors.* See Nos. 017033, 054771, and 069043 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* 6.25 mg/lb (1 mL/10 lb of body weight) twice a day. Skin and soft tissue infections such as abscesses, cellulitis, wounds, superficial/juvenile pyoderma, and periodontal infections should be treated for 5 to 7 days or for 48 hours after all signs have subsided. If no

response is seen after 5 days of treatment, therapy should be discontinued and the case reevaluated. Deep pyoderma may require treatment for 21 days; the maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections such as wounds, abscesses, cellulitis, superficial/juvenile and deep pyoderma due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus,* non-beta-lactamase-producing *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., and *Escherichia coli.* Treatment of periodontal infections due to susceptible strains of both aerobic and anaerobic bacteria.

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

(2) *Cats*—(i) *Amount.* 62.5 mg (1 mL) twice daily. Skin and soft tissue infections such as abscesses and cellulitis/dermatitis should be treated for 5 to 7 days or 48 hours after all symptoms have subsided, not to exceed 30 days. If no response is seen after 3 days of treatment, therapy should be discontinued and the case reevaluated. Urinary tract infections may require treatment for 10 to 14 days or longer. The maximum duration of treatment should not exceed 30 days.

(ii) *Indications for use.* Treatment of skin and soft tissue infections, such as wounds, abscesses, and cellulitis/dermatitis due to susceptible strains of the following organisms: Beta-lactamase-producing *Staphylococcus aureus,* non-beta-lactamase-producing *Staphylococcus aureus, Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli, Pasteurella multocida,* and *Pasteurella* spp. Urinary tract infections (cystitis) due to susceptible strains of *E. coli.*

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

■ 7. In § 520.2090, revise paragraph (c)(2) to read as follows:

§ 520.2090 Sarolaner, moxidectin, and pyrantel.

* * * * *

(c) * * *

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment and control of roundworm (immature adult and adult *Toxocara canis* and adult *Toxascaris leonina*) and hookworm (L4, immature adult, and adult *Ancylostoma caninum* and adult *Uncinaria stenocephala*) infections. Kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment and prevention of flea infestations, and the treatment and control of tick infestations with *Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick) for 1 month in dogs and puppies 8 weeks of age and older, and weighing 2.8 pounds or greater. For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

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■ 8. In § 520.2455:

■ a. Revise paragraphs (b)(1) through (4); and

■ b. In paragraph (d)(2), remove ''semduramycin'' and in its place add ''semduramicin.''

The revisions read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(1) No. 058198 for products described in paragraph (a) of this section.

(2) No. 066104 for product described in paragraph (a)(1) of this section.

(3) Nos. 016592, 051311, and 061133 for product described in paragraph (a)(2) of this section.

(4) No. 054771 for product described in paragraph (a)(3) of this section.

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PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 10. In § 522.246, revise paragraphs (b)(2) and (3) to read as follows:

§ 522.246 Butorphanol.

* * * * *

(b) * * *

(2) No. 043264 for use of the product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) Nos. 000061, 043264, and 059399 for use of the product described in paragraph (a)(3) of this section as in paragraph (d)(3) of this section.

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§ 522.533 [Amended]

■ 11. In § 522.533, in paragraph (b)(2), remove ''051330'' and in its place add ''043264''.

■ 12. In § 522.690:

■ a. Revise paragraphs (a) and (b);

■ b. Revise paragraph (d)(1) introductory text and paragraph (d)(1)(i);

■ c. Add paragraph (d)(2) introductory text;

■ d. Revise paragraph (d)(2)(ii);

■ e. Add paragraph (d)(3) introductory text;

■ f. Revise paragraph (d)(3)(ii); and

■ g. Remove paragraph (d)(4).

The revisions and additions read as follows:

§ 522.690 Dinoprost.

(a) *Specifications.* Each milliliter (mL) of solution contains dinoprost tromethamine equivalent to:

(1) 5 milligrams (mg) dinoprost; or

(2) 12.5 mg dinoprost.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 054771 and 061133 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

(2) No. 054771 for use of product described in paragraph (a)(2) as in paragraph (d)(1) of this section.

* * * * *

(d) * * *

(1) *Cattle.* Administer products described in paragraph (a) of this section as follows:

(i) *Amount.* 25 mg as an intramuscular injection of the 5 mg/mL product or as an intramuscular or subcutaneous injection of the 12.5 mg/mL product.

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(2) * * * Administer product described in paragraph (a)(1) of this section as follows:

* * * * *

(ii) *Indications for use.* (A) For controlling the timing of estrus in estrous cycling mares.

(B) For difficult-to-breed mares (clinically anestrous mares that have a corpus luteum).

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(3) * * * Administer product described in paragraph (a)(1) of this section as follows:

* * * * *

(ii) *Indications for use.* For parturition induction in swine.

■ 13. In § 522.812, revise paragraph (b)(2) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(2) Nos. 055529, 058005, 058198, and 061133 for use of product described in paragraph (a)(2) of this section as in paragraphs (e)(2) and (3) of this section.

* * * * *

§ 522.955 [Amended]

■ 14. In § 522.955, in paragraph (b)(3), remove ''No. 086050'' and in its place

add ''Nos. 058005 and 086050''; and in paragraph (d)(1)(ii)(C), remove ''No. 000061'' and in its place add ''Nos. 000061, 058005, and 086050''.

■ 15. In § 522.1077, revise paragraph (d)(1)(iv) to read as follows:

§ 522.1077 Gonadorelin.

* * * * *

(d) * * *

(1) * * *

(iv) Dinoprost injection for use as in paragraph (e)(1)(vi) of this section as provided by Nos. 054771 and 061133 in § 510.600(c) of this chapter.

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■ 16. In § 522.1940, revise the paragraph (c)(1) heading, paragraph (c)(1)(iii), the paragraph (c)(2) heading, and paragraph (c)(2)(iii) to read as follows:

§ 522.1940 Progesterone and estradiol benzoate.

* * * * *

(c) * * *

(1) *Suckling beef calves at least 45 days old and up to 400 lb of body weight*—* * *

* * * * *

(iii) *Limitations.* For subcutaneous ear implantation, one dose per animal. Do not use in beef calves less than 45 days of age, dairy calves, and veal calves because effectiveness and safety have not been established. Do not use in animals intended for subsequent breeding, or in dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Growing beef steers weighing 400 lb or more*—* * *

* * * * *

(iii) *Limitations.* For subcutaneous ear implantation, one dose per animal. Do not use in beef calves less than 45 days of age, dairy calves, and veal calves because effectiveness and safety have not been established. Do not use in animals intended for subsequent breeding, or in dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

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■ 17. In § 522.2343, revise paragraph (c) introductory text and paragraph (c)(3) to read as follows:

§ 522.2343 Testosterone propionate and estradiol benzoate.

* * * * *

(c) *Conditions of use.* For implantation in growing beef heifers weighing 400 lb or more as follows:

* * * * *

(3) *Limitations.* For subcutaneous ear implantation, one dose per animal. Not for use in dairy or beef replacement heifers. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because safety and effectiveness have not been established. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

■ 18. In § 522.2478, redesignate paragraph (d)(3) as paragraph (d)(4); add new paragraph (d)(3); and revise newly redesignated paragraph (d)(4) heading and paragraph (d)(4)(i)(C) to read as follows:

§ 522.2478 Trenbolone acetate and estradiol benzoate.

* * * * *

(d) * * *

(3) *Growing beef steers and heifers fed in confinement for slaughter.* (i) For an implant as described in paragraph (a)(2)(ii) of this section:

(A) *Amount.* 150 mg trenbolone acetate and 21 mg estradiol benzoate in an extended-release implant.

(B) *Indications for use.* For increased rate of weight gain for up to 200 days.

(C) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within each separate production phase. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in 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.

(ii) [Reserved]

(4) *Growing beef steers and heifers on pasture (stocker, feeder, and slaughter).* (i) * * *

(C) *Limitations.* Implant pellets subcutaneously in ear only. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant within each separate production phase. Safety and effectiveness following reimplantation have not been evaluated. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves because effectiveness and safety have not been established. Do not use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in 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.

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■ 19. In 522.2630, revise paragraphs (b)(1) and (2) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(1) Nos. 013744, 051311, 054771, 058198, and 061133 for use of product described in paragraph (a)(1) as in paragraphs (d)(1)(i) and (ii), (d)(1)(iii)(A), and (d)(2) of this section.

(2) Nos. 013744, 051311, and 054771 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

■ 20. In § 522.2662, revise paragraph (b)(3) to read as follows:

§ 522.2662 Xylazine.

* * * * *

(b) * * *

(3) Nos. 043264 and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section; and product described in paragraph (a)(2) of this section as in paragraphs (d)(2), (d)(3)(i), (d)(3)(ii)(A), and (d)(3)(iii) of this section.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 22. In § 524.1146, revise paragraphs (b)(2) and (3) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(2) Nos. 051072, 017030, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

(3) Nos. 051072 and 058198 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(3) of this section.

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PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 23. The authority citation for part 529 continues to read as follows:

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

■ 24. In § 529.1940, revise the last sentence in paragraph (e)(1)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(e) * * *

(1) * * *

(iii) * * * Dinoprost injection for use as in paragraphs (e)(1)(ii)(A) and (B) of this section as in § 522.690 of this chapter, provided by Nos. 054771 and 061133 in § 510.600(c) of this chapter.

* * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 25. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

■ 26. In 556.240, revise paragraphs (b)(1) and (c) to read as follows:

§ 556.240 Estradiol and related esters.

* * * * *

(b) * * *

(1) *Cattle.* (i) Muscle: 0.2 ppb.

(ii) Liver: 0.6 ppb.

(iii) Kidney: 1.2 ppb.

(iv) Fat: 1.2 ppb.

* * * * *

(c) *Related conditions of use.* See §§ 522.840, 522.850, 522.1940, 522.2343, 522.2477, and 522.2478 of this chapter.

■ 27. In § 556.370, revise paragraph (b) to read as follows:

§ 556.370 Lubabegron.

* * * * *

(b) *Tolerances.* The tolerances for lubabegron (marker residue) are:

(1) *Cattle.* (i) Liver (target tissue): 10 ppb.

(ii) Muscle: 3 ppb.

(iii) Kidney: 20 ppb.

(2) [Reserved]

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 29. In § 558.254, revise paragraph (e) to read as follows:

§ 558.254 Famphur.

* * * * *

(e) *Conditions of use.* It is used in cattle feed as follows:

Famphur amount	Indications for use	Limitations	Sponsor
(1) To provide 1.1 milligrams per pound (mg/lb) body weight per day.	Beef cattle and nonlactating dairy cattle: For control of grubs and as an aid in control of sucking lice.	Feed for 30 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter.	000061
(2) To provide 2.3 mg/lb body weight per day.	Beef cattle and nonlactating dairy cattle: For control of grubs.	Feed for 10 days. Withdraw from dry dairy cows and heifers 21 days prior to freshening. Withdraw 4 days prior to slaughter.	000061

■ 30. In § 558.355, revise paragraphs (d)(8)(vi) and (f)(1)(ii), (iv), and (vi) to read as follows:

§ 558.355 Monensin.

* * * * *

(d) * * *

(8) * * *

(vi) Not for replacement chickens intended to become broiler breeding chickens.

* * * * *

(f) * * *

(1) * * *

Monensin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 90 to 110		Layer replacement chickens: As an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*	Feed continuously as the sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens.	058198
*	*	*	*	*
(iv) 90 to 110	Bacitracin methylenedisalicylate, 4 to 50.	Layer replacement 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 increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*
(vi) 90 to 110	Bacitracin methylenedisalicylate, 50.	Broiler and layer replacement 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 improved feed efficiency, and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Do not feed to chickens over 16 weeks of age. Do not feed to laying chickens. Monensin sodium provided by No. 058198, bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*

* * * * *

■ 31. In § 558.500, revise paragraphs (b) and (e)(2)(i), (iii), and (vi) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 058198: Type A medicated articles containing 9 or 45.4 grams per pound (g/lb) ractopamine hydrochloride.

(2) Nos. 016592, 051311, and 054771: Type A medicated articles containing 45.4 g/lb ractopamine hydrochloride.

* * * * *

(e) * * *

(2) * * *

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	016592 051311 054771 058198
*	*	* *	* * *	
(iii) 9.8 to 24.6		Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	016592 051311 054771 058198
*	*	* *	* * *	
(vi) Not to exceed 800; to provide 70 to 400 mg/head/day.		Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Top dress ractopamine at a minimum of 1.0 lb/head/day of medicated feed continuously during the last 28 to 42 days on feed. Not for animals intended for breeding..	016592 051311 054771 058198
*	*	* *	* * *	

* * * * *

§ 558.555 [Amended]

■ 32. In § 558.555, in paragraph (f), remove ''Semduramycin'' and in its place add ''Semduramicin''.

■ 33. In § 558.633, revise paragraph (d)(3) to read as follows:

§ 558.633 Tylvalosin.

* * * * *

(d) * * *

(3) Pelleted Type C medicated feeds must bear an expiration date of 30 days after the date of manufacture. Crumbled Type C medicated feeds must bear an expiration date of 7 days after the date of manufacture.

* * * * *

■ 34. In § 558.680, revise paragraphs (d)(1)(iii), (iv), (vii), and (viii) and (d)(2) to read as follows:

§ 558.680 Zoalene.

* * * * *

(d) * * *

(1) * * *

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* * *	
(iii) 36.3 to 113.5	Bacitracin methylenedisalicylate, 50.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as the sole ration as in the subtable in item (i). Grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 058198
(iv) 36.3 to 113.5	Bacitracin methylenedisalicylate, 100 to 200.	Replacement chickens: For development of active immunity to coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in the subtable in item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 058198
*	*	* *	* * *	
(vii) 113.5	Bacitracin methylenedisalicylate, 50.	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as the sole ration. Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 058198
(viii) 113.5	Bacitracin methylenedisalicylate,. 100 to 200	Broiler chickens: For prevention and control of coccidiosis; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771 058198
*	*	* *	* * *	

(2) *Turkeys*—

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 113.5 to 170.3		Growing turkeys: For prevention and control of coccidiosis.	Feed continuously as sole ration. For turkeys grown for meat purposes only. Not to be fed to laying birds.	054771 058198
(ii) 113.5 to 170.3	Bacitracin methylenedisalicylate, 4 to 50.	Growing turkeys: For prevention and control of coccidiosis; and for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration until 14 to 16 weeks of age. For turkeys grown for meat purposes only. Not to be fed to laying birds.	054771 058198

* * * * *

Dated: March 21, 2022.

Andi Lipstein Fristedt,

Deputy Commissioner for Policy, Legislation, and International Affairs, U.S. Food and Drug Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 822

[Docket No. FDA–2021–N–0246]

Medical Devices; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending its medical device regulations to update mailing address information and to reduce (from three to one) the number of copies of certain documents that need to be submitted to FDA. The rule does not impose any new regulatory requirements on affected parties. This action is editorial in nature and is intended to improve the accuracy of the Agency's regulations, and to remove a submission requirement that is no longer necessary.

DATES: This rule is effective March 29, 2022.

FOR FURTHER INFORMATION CONTACT: Madhusoodana Nambiar, Office of Policy, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 5519, Silver Spring, MD 20993–0002, 301–796–5837.

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Center for Devices and Radiological Health (CDRH) has reorganized to create an agile infrastructure that can adapt to future organizational, regulatory, and scientific needs (84 FR 22854, May 20, 2019; 85 FR 18439, April 2, 2020). The newly formed Office of Product Evaluation and Quality (OPEQ) combined the former Office of Compliance, the Office of Device Evaluation, the Office of Surveillance and Biometrics, and the Office of In Vitro Diagnostics and Radiological Health, with a focus on a Total Product Lifecycle (TPLC) approach to medical device oversight. Within OPEQ there are Offices of Health Technology that focus on the TPLC review of specific types of medical devices as well as cross-cutting offices focusing on specific policy and programmatic needs including the Office of Regulatory Programs and the Office of Clinical Evidence and Analysis. As part of this technical amendment, we are making a change to correctly identify the address for obtaining particular information. We are also amending the requirement for the submission of multiple copies of certain documents to a single copy, as FDA's receipt of multiple copies is no longer necessary. The changes published in this notice are non-substantive and editorial in nature.

II. Description of the Technical Amendments

One regulation specified in this notice is being revised to make a non-substantive editorial change to update particular mailing address information. For the other two regulations specified in this notice, we are removing the requirements for submission of multiple copies of certain postmarket surveillance-related documents, to instead require submission of only one copy, because the requirement for multiple copies is no longer necessary. The rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA). The APA generally exempts ''rules of agency organization, procedure, or practice'' from the requirements of notice and comment rulemaking. (5 U.S.C. 553(b)(A)). Rules are also generally exempt from such requirements when an Agency ''for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements. All the revisions FDA publishes through this notice make technical or non-substantive changes. Some of these revisions pertain solely to the CDRH reorganization, and constitute ''rules of agency organization, procedure, or practice'' not subject to the requirements of notice and comment under 5 U.S.C. 553(b)(A). The balance of these revisions reduces (from three to one) the number of copies of certain documents that need to be submitted to FDA. Such technical, non-substantive change is ''a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' (*Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012)) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for this reduction in the number of copies of certain documents that must be submitted.

The APA allows an effective date less than 30 days after publication as ''provided by the agency for good cause found and published with the rule'' (5 U.S.C. 553(d)(3)). An effective date 30 or more days from the date of publication is unnecessary in this case because the amendments do not impose any new regulatory requirements on affected parties, and affected parties do not need time to ''adjust to the new regulation'' before the rule takes effect (*Am. Federation of Government Emp., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981)). Therefore, FDA finds good cause for the amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 822

Medical devices, Reporting and recordkeeping requirements.