(iv) Replace Fig. 11 with paragraph (b)(5)(v), ''Fig. 12''.

(v) *Fig. 12: Suffocation Hazard Warning.*

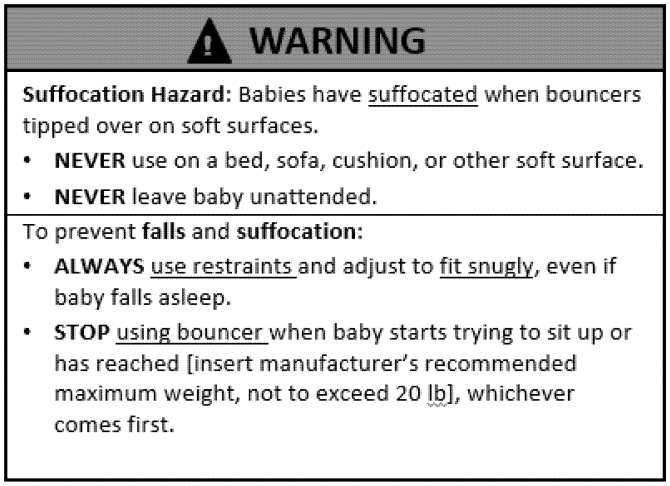

Fig. 12 Suffocation Hazard Warning

(vi) Replace Fig. 12 with paragraph (b)(5)(vii), ''Fig. 13''.

(vii) *Fig. 13: Instruction Warning Statements.*

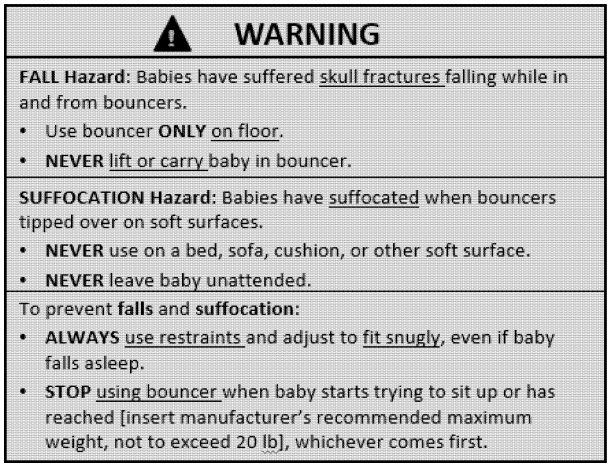

Fig. 13 Instruction Warning Statements

(6) In section 9.2.2 of ASTM F2167–17, replace the reference to ''Fig. 12'' with ''Fig. 13.''

Alberta E. Mills,

Acting Secretary, Consumer Product Safety Commission.

[FR Doc. 2017–19255 Filed 9–15–17; 8:45 am]

BILLING CODE 6355–01–P

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; Change of Sponsor's Address

AGENCY: Food and Drug Administration, 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 a new animal drug application (NADA) and abbreviated new animal drug applications (ANADAs) during March and April 2017. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of a sponsor's address and to make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective September 18, 2017.

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. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for a NADA and ANADAs during March and April 2017, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Dockets Management Staff Office (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the internet may obtain these documents at the CVM FOIA Electronic Reading Room: *https://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: *https://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MARCH AND APRIL 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 24, 2017 ...	141–269	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	REVALOR–XH (trenbolone acetate and estradiol extended-release implant).	Cattle	Supplemental approval of a new implant for increased rate of weight gain and improved feed efficiency for up to 200 days after implantation in beef heifers fed in confinement for slaughter.	FOI Summary, EA/FONSI.[1]
April 19, 2017 ...	200–593	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210–B, Durham, NC 27703.	Carprofen Injection.	Dogs	Original approval as a generic copy of NADA 141–199.	FOI Summary.
April 28, 2017 ...	200–595	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	CARPRIEVE (carprofen) Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.

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

II. Technical Amendments

Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405, has informed FDA that it has changed its address to 1800 Sir Tyler Dr., Wilmington, NC 28405. Accordingly, we are amending § 510.600(c) to reflect this change.

We are making several technical amendments in part 558, which was amended on December 27, 2016 (81 FR 94991), and February 24, 2017 (82 FR 11510), as part of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative. We are also making several technical amendments to the regulations for dosage form drugs. These actions are being taken to improve the accuracy of the regulations.

III. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (the 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 Parts 520, 522, and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1), revise the entry for ''Pharmgate LLC''; and in the table in paragraph (c)(2), revise the entry for ''069254'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * *	
Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
069254	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405
* * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.88g [Amended]

■ 4. In § 520.88g, in paragraphs (c)(1)(ii) and (c)(2)(ii), in the first sentence, remove ''nonbeta-lactamase'' and in its place add ''non-beta-lactamase''.

■ 5. In § 520.304, remove paragraph (b)(3) and revise paragraphs (b)(1) and (2) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(1) Nos. 054771, 026637, 055529, and 062250 for use of products described in paragraph (a) as in paragraph (d) of this section.

(2) No. 000859 for use of product described in paragraph (a)(1) as in paragraph (d) of this section.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

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

§ 522.304 Carprofen.

* * * * *

(b) *Sponsors.* See Nos. 016729, 026637, 054771, and 055529 in § 510.600(c) of this chapter.

* * * * *

■ 8. In § 522.970, revise paragraph (b)(1); remove paragraphs (b)(3), (e)(2)(ii)(B), and (e)(2)(iii); and add two sentences after the italic heading of paragraph (e)(2)(ii), to read as follows:

§ 522.970 Flunixin.

* * * * *

(b) * * *

(1) See Nos. 000061, 000859, 055529, 057561, and 061623 for use as in paragraph (e) of this section.

* * * * *

(e) * * *

(2) * * *

(ii) *Limitations.* Approved only for intravenous administration in cattle. Intramuscular administration has resulted in violative residues in the edible tissues of cattle sent to slaughter. * * *

* * * * *

■ 9. In § 522.1002, revise paragraph (b)(1) to read as follows:

§ 522.1002 Follicle stimulating hormone.

* * * * *

(b)(1) *Specifications*—(i) *Single pack.* 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 constituted, each milliliter of solution contains 35 IU FSH.

(ii) *Dual pack.* Each package contains 2 vials. Each vial contains 700 international units (IU) porcine-pituitary-derived FSH equivalent to 400 milligrams NIH–FSH–P1, as a dry powder. Constitute with 20 mL bacteriostatic sodium chloride injection, using strict aseptic technique. When constituted, each milliliter of solution contains 35 IU FSH.

* * * * *

■ 10. In § 522.1660a, revise the first sentence of paragraph (e)(1)(ii) to read as follows:

§ 522.1660a Oxytetracycline solution, 200 milligrams/milliliter.

* * * * *

(e) * * *

(1) * * *

(ii) *Limitations.* Exceeding the highest recommended level of drug per pound of bodyweight per day, administering more than the recommended number of treatments, and/or exceeding 10 mL intramuscularly or subcutaneously per injection site in adult beef and dairy cattle may result in antibiotic residues beyond the withdrawal time. * * *

* * * * *

■ 11. In § 522.2477, revise paragraph (b)(2) and the first sentence in paragraphs (d)(1)(iii), (d)(2)(iii), (d)(3)(iii), and (d)(4)(iii); and add paragraph (d)(5) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(b) * * *

(2) No. 000061 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(i)(G), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(i)(C), (d)(2)(i)(D), (d)(2)(ii), (d)(2)(iii), (d)(3)(i)(A), (d)(3)(ii), (d)(3)(iii), (d)(4), and (d)(5) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Administer implant subcutaneously in the ear only. * * *

(2) * * *

(iii) *Limitations.* Administer implant subcutaneously in the ear only. * * *

(3) * * *

(iii) *Limitations.* Administer implant subcutaneously in the ear only. * * *

(4) * * *

(iii) *Limitations.* Administer implant subcutaneously in the ear only. * * *

(5) *Beef heifers fed in confinement for slaughter*—(i) *Amount.* Each extended-release implant contains 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 6 coated and 4 uncoated pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol).

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

(iii) *Limitations.* Administer implant subcutaneously in the ear only. Do not use in lactating dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Do not use in calves to be processed for veal. A withdrawal period has not been established for this product in pre-ruminating calves. Effectiveness

and animal safety in veal calves have not been established. Not approved for repeated implantation (reimplantation) with this or any other cattle ear implant during the production phase(s) identified on labeling (beef heifers fed in confinement for slaughter) unless otherwise indicated on labeling because safety and effectiveness have not been evaluated.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 13. In § 524.998, add paragraph (c)(2) to read as follows:

§ 524.998 Fluralaner.

* * * * *

(c) * * *

(2) *Cats*—(i) *Amount.* Administer topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 18.2 mg/lb (40 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *D. variabilis* ticks.

(ii) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*C. felis*) and the treatment and control of *I. scapularis* (black-legged tick) infestations for 12 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater; for the treatment and control of *D. variabilis* (American dog tick) infestations for 8 weeks in cats and kittens 6 months of age and older, and weighing 2.6 lb or greater.

(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

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

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

■ 15. In § 558.4, in paragraph (d), in the ''Category II'' table, revise the row entries for ''Neomycin'' and ''Oxytetracycline'' to read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent Type A [1]	Type B maximum (100x)	Assay limits percent Type B/C [2]
* * *	*	* *	*
Neomycin	80–120	20 g/lb (4.4%)	70–125
Oxytetracycline	80–120	20 g/lb (4.4%)	65–135
* * *	*	* *	*

[1] Percent of labeled amount.

[2] Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limit, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make a Type C medicated feed.

* * * * *

§ 558.128 [Amended]

■ 16. In § 558.128, in paragraphs (e)(4)(iii) and (xii) and (e)(5)(ii) and (iii), in the ''Sponsor'' column, add ''069254'' after ''054771''; in paragraphs (e)(4)(xi) and (xiii), in the ''Limitations'' column, remove the third sentence ''Withdraw 24 hours prior to slaughter.''; and in paragraph (e)(6)(v), remove ''*Sponsor.* See No. 054771'' and in its place add ''*Sponsors.* See Nos. 054771 and 069254''.

§ 558.625 [Amended]

■ 17. Amend § 558.625 as follows:

■ a. In paragraphs (e)(1)(vii) and (ix), in the ''Tylosin grams/ton'' column, remove ''40 to 100'' and in its place add ''40 or 100'';

■ b. In paragraph (e)(2)(ii), in the ''Limitations'' column, add ''See §§ 558.311(d) and 558.342(d) in this chapter.'' after the last sentence;

■ c. In paragraph (e)(2)(iii), in the ''Limitations '' column, add ''See § 558.342(d) in this chapter.'' after the last sentence;

■ d. In paragraph (e)(2)(vi), in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter'' and in its place add ''See §§ 558.311(d) and 558.355(d) in this chapter.'';

■ e. In paragraph (e)(2)(vii), in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter'' and in its place add ''See §§ 558.342(d) and 558.355(d) in this chapter.'';

■ f. In paragraphs (e)(2)(viii), (ix), and (x), in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter'' and in its place add ''See §§ 558.355(d) and 558.500(d) in this chapter.''

■ g. In paragraph (e)(2)(xi) in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter.'' and in its place add ''See §§ 558.342(d), 558.355(d), and 558.500(d) in this chapter.'';

■ h. In paragraphs (e)(2)(xii) and (xiii), in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter.'' and in its place add ''See §§ 558.355(d) and 558.665(d) in this chapter.''; and

■ i. In paragraphs (e)(2)(xiv) and (xv), in the ''Limitations'' column, remove ''See § 558.355(d) in this chapter.'' and in its place add ''See §§ 558.342(d), 558.355(d) and 558.665(d) in this chapter.''

Dated: September 7, 2017.

Anna K. Abram,

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

[FR Doc. 2017–19602 Filed 9–15–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2017–0864]

RIN 1625–AA08

Regattas and Marine Parades; Great Lakes Annual Marine Events

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.