expressed as ''Estimated Energy Cost'' in dollars and based on usage of 3 hours per day and 11 cents ($0.11) per kWh.

(2) *Principal display panel format.* The light output (brightness) and energy cost shall appear in that order and with equal clarity and conspicuousness on the principal display panel of the product package. The format, terms, specifications, and minimum sizes shall follow the specifications and minimum sizes displayed in Prototype Label 5 in appendix L of this part.

(3) *Lighting Facts label content.* The side or rear display panel of the product package shall be labeled clearly and conspicuously with a Lighting Facts label that contains the following information in the following order:

(i) The light output of each lamp included in the package, expressed as ''Brightness'' in average initial lumens rounded to the nearest five;

(ii) The estimated annual energy cost of each lamp included in the package based on the average initial wattage, a usage rate of 3 hours per day and 11 cents ($0.11) per kWh and explanatory text as illustrated in Prototype Label 6 in appendix L of this part;

(iii) The life, as defined in § 305.2(w), of each lamp included in the package, expressed in years rounded to the nearest tenth (based on 3 hours operation per day);

(iv) The correlated color temperature of each lamp included in the package, as measured in degrees Kelvin and expressed as ''Light Appearance'' and by a number and a marker in the form of a scale as illustrated in Prototype Label 6 to appendix L of this part placed proportionately on the scale where the left end equals 2,600 K and the right end equals 6,600 K;

(v) The wattage, as defined in § 305.2(hh), for each lamp included in the package, expressed as energy used in average initial wattage;

(vi) The ENERGY STAR logo as illustrated in Prototype Label 6 to appendix L of this part for certified products, if desired by the manufacturer or private labeler. Only manufacturers or private labelers that have signed a Memorandum of Understanding with the Department of Energy or the Environmental Protection Agency may add the ENERGY STAR logo to labels on certified covered products; such manufacturers or private labelers may add the ENERGY STAR logo to labels only on those products that are covered by the Memorandum of Understanding;

(vii) The design voltage of each lamp included in the package, if other than 120 volts;

(viii) For any general service lamp containing mercury, the following statement: ''Contains Mercury For more on clean up and safe disposal, visit *epa.gov/cfl.*'' The manufacturer may also print an ''Hg[Encircled]'' symbol on the label after the term ''Contains Mercury''; and

(ix) No marks or information other than that specified in this part shall appear on the Lighting Facts label.

(4) *Standard Lighting Facts label format.* Except as provided in paragraph (b)(5) of this section, information specified in paragraph (b)(3) of this section shall be presented on covered lamp packages in the format, terms, explanatory text, specifications, and minimum sizes as shown in Prototype Labels 6 in appendix L of this part and consistent in format and orientation with Sample Labels 10, 11, or 12 in appendix L. The text and lines shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(i) The Lighting Facts information shall be set off in a box by use of hairlines and shall be all black or one color type, printed on a white or other neutral contrasting background whenever practical.

(ii) All information within the Lighting Facts label shall utilize:

(A) Arial or an equivalent type style;

(B) Upper and lower case letters;

(C) Leading as indicated in Prototype Label 6 in appendix L of this part;

(D) Letters that never touch;

(E) The box and hairlines separating information as illustrated in Prototype Labels 6 in appendix L of this part; and

(F) The minimum font sizes and line thicknesses as illustrated in Prototype Label 6 in appendix L of this part.

(5) *Lighting Facts format for small packages.* If the total surface area of the product package available for labeling is less than 24 square inches and the package shape or size cannot accommodate the standard label required by paragraph (b)(4) of this section, manufacturers may provide the information specified in paragraph (b)(3) of this section using a smaller, linear label following the format, terms, explanatory text, specifications, and minimum sizes illustrated in Prototype Label 7 in appendix L of this part.

(6) *Bilingual labels.* The information required by paragraphs (b)(1) through (5) of this section may be presented in a second language either by using separate labels for each language or in a bilingual label with the English text in the format required by this section immediately followed by the text in the second language. Sample Label 13 in appendix L of this part provides an example of a bilingual Lighting Facts label. All required information must be included in both languages. Numeric characters that are identical in both languages need not be repeated.

(7) *Product labeling.* Any general service lamp shall be labeled legibly on the product with the following information:

(i) The lamp's average initial lumens, expressed as a number rounded to the nearest five, adjacent to the word ''lumens,'' both provided in minimum 8 point font; and

(ii) For general service lamps containing mercury, the following statement: ''Mercury disposal: *epa.gov/cfl*'' in minimum 8 point font.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2018–06694 Filed 4–4–18; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 526, and 558

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsorship; Change of a Sponsor's Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

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 2017. 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 reflect changes of sponsorship of applications and a change of a sponsor's name and address.

DATES: This rule is effective April 5, 2018.

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 NADAs and ANADAs during October, November, and December 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 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 (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 OCTOBER, NOVEMBER, AND DECEMBER 2017

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 27, 2017.	141–467	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Avilamycin and narasin Type C medicated feeds.	Chickens	Original approval for use of INTREPITY (avilamycin) and MONTEBAN (narasin) Type A medicated articles to manufacture Type C medicated broiler chicken feeds for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens,* and the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.*	FOI Summary; EA/FONSI. [1]
October 27, 2017.	141–466	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	Avilamycin, narasin, and nicarbazin Type C medicated feeds.	Chickens	Original approval for use of INTREPITY (avilamycin) and MAXIBAN (narasin and nicarbazin) Type A medicated articles to manufacture Type C medicated broiler chicken feeds for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens,* and the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati, and E. maxima.*	FOI Summary; EA/FONSI. [1]
November 9, 2017.	106–111	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	TELAZOL (tiletamine and zolazepam for injection).	Dogs	Supplemental approval for intravenous administration in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.	FOI Summary.
November 21, 2017.	200–473	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	TYLOVET (tylosin tartrate) Soluble Powder.	Chickens	Supplemental approval for the control of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.	FOI Summary.
November 30, 2017.	097–505	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	Lincomycin Type B and Type C medicated feeds.	Swine	Supplemental approval for use of LINCOMIX (lincomycin) Type A medicated articles to manufacture Type B and Type C medicated swine feeds for reduction in the severity of the effects of respiratory disease associated with *Mycoplasma hyopneumoniae.*	
December 11, 2017.	141–441	Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137.	IVERHART MAX (ivermectin, pyrantel pamoate, praziquantel) Soft Chew.	Dogs	Original approval of a soft chewable tablet to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for a month (30 days) after infection and for the treatment and control of roundworm (*Toxocara canis, Toxascaris leonina*), hookworm (*Ancylostoma caninum, Uncinaria stenocephala, Ancylostoma braziliense*), and tapeworm (*Dipylidium caninum, Taenia pisiformis*) infections.	FOI Summary.
December 12, 2017.	200–617	Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405.	Chlortetracycline and lasalocid Type B and Type C medicated feeds.	Cattle	Original approval for use of DERACIN (chlortetracycline) and BOVATEC (lasalocid) Type A medicated articles to manufacture Type B and Type C medicated cattle feeds as a generic copy of NADA 141–250.	

[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. Changes of Sponsorship

Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211 has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140:

File No.	Product name	21 CFR section
141–455	GALLIPRANT (grapiprant) Tablets	520.1084

Strategic Veterinary Pharmaceuticals, Inc., 100 NW Airport Rd., St. Joseph, MO 64503 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to HQ Specialty Pharma Corp., 120 Rte. 17 North, suite 130, Paramus, NJ 07652:

File No.	Product name	21 CFR section
055–097	DRY–MAST (pen G procaine/dihydrostreptomycin sulfate) Infusion	526.1696b

Ridley Block Operations Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Ridley USA, Inc., 111 W Cherry St., suite 500, Mankato, MN 56001:

File No.	Product name	21 CFR section
141–187	CRYSTALYX IONO–LYX (lasalocid) Type C Medicated Protein Block	558.311

Ridley U.S. Holdings, Inc., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500 has informed FDA that it has transferred ownership of, and all rights and interest in, the following application to Ridley USA, Inc., 111 W Cherry St., suite 500, Mankato, MN 56001:

File No.	Product name	21 CFR section
033–733	SWEETLIX BLOAT–GUARD (poloxalene) Pressed Block	520.1840

Accordingly, the animal drug regulations are being amended to reflect these changes of sponsorship. Following these withdrawals of approval, neither Ridley Block Operations, Inc. nor Ridley U.S. Holdings, Inc. is the sponsor of an approved application. Accordingly, these firms will be removed from the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

III. 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 Parts 520, 522, and 526

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, 21 CFR parts 510, 520, 522, 526, 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), remove the entry for ''Ridley Block Operations, Inc.'' and revise the entry for ''Ridley U.S. Holdings, Inc.''; and in the table in paragraph (c)(2), remove the entry for ''068287'' and revise the entry for ''067949''.

The revisions 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
* * * * * * *	
Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001	067949
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
067949	Ridley USA, Inc., 111 W Cherry St., Suite 500, Mankato, MN 56001.
* * * * * * *	

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.

§ 520.1084 [Amended]

■ 4. In § 520.1084, in paragraph (b), remove ''086026'' and in its place add ''058198''.

§ 520.1199 [Amended]

■ 5. In § 520.1199, in paragraph (a) introductory text, remove ''chewable tablet'' and in its place add ''chewable tablet or soft chewable tablet''; and in paragraph (c)(2), remove ''Prevents'' and in its place add ''To prevent''.

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

§ 520.2640 Tylosin.

* * * * *

(b) * * *

(1) Nos. 016592 and 058198 for use as in paragraph (e) of this section.

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

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 8. In § 522.2470, revise paragraphs (b) and (c) to read as follows:

§ 522.2470 Tiletamine and zolazepam for injection.

* * * * *

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

(1) No. 054771 for use as in paragraph (c) of this section.

(2) Nos. 026637 and 051311 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii)(A), (c)(1)(iii) and (c)(2) of this section.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Expressed as milligrams of the drug combination:

(A) An initial intramuscular dosage of 3 to 4.5 milligrams per pound (mg/lb) of body weight for diagnostic purposes; 4.5 to 6 mg/lb of body weight for minor procedures of short duration such as repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 mg/lb of body weight. The maximum total safe dose is 13.6 mg/lb of body weight.

(B) Administer intravenously at 1 to 2 mg/lb (2.2 to 4.4 mg/kg) body weight to effect for induction of anesthesia followed by maintenance with an inhalant anesthetic.

(ii) *Indications for use.* (A) Intramuscular administration in dogs for restraint and minor procedures of short duration (30 minutes average) requiring mild to moderate analgesia.

(B) Intravenous administration in dogs for induction of anesthesia followed by maintenance with an inhalant anesthetic.

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

(2) *Cats*—(i) *Amount.* An initial intramuscular dosage of 4.4 to 5.4 mg/lb of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 mg/lb of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 mg/lb of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 mg/lb of body weight.

(ii) *Indications for use.* For restraint or for anesthesia combined with muscle relaxation.

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

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 9. The authority citation for part 526 continues to read as follows:

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

§ 526.1696b [Amended]

■ 10. In § 526.1696b, in paragraph (b), remove ''054628'' and in its place add ''042791''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 12. In § 558.68, add paragraphs (e)(1)(iii) and (iv) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *

(1) * * *

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(iii) 13.6 to 40.9	Narasin, 54 to 90	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed as the sole ration for 21 consecutive days to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Narasin as provided by No. 058198 in § 510.600(c) of this chapter.	058198
(iv) 13.6 to 40.9	Narasin 27 to 45; nicarbazin 27 to 45	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens;* and for the prevention of coccidiosis caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima*.	Feed as the sole ration for 21 consecutive days to chickens that are at risk of developing, but not yet showing clinical signs of, necrotic enteritis associated with *Clostridium perfringens.* To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Do not feed to laying hens. Withdraw 5 days before slaughter. Narasin and nicarbazin as provided by No. 058198 in § 510.600(c) of this chapter.	058198

* * * * *

§ 558.128 [Amended]

■ 13. In § 558.128, in paragraph (e)(4), in the ''Sponsor'' column, numerically add ''069254'' to paragraphs (e)(4)(ii), (vii), (viii), (ix), and (xviii) through (xxvi).

§ 558.311 [Amended]

■ 14. In § 558.311, in paragraph (b)(9) and in paragraph (e)(1)(xix), in the ''Sponsor'' column, remove ''068287'' and in its place add ''067949''.

■ 15. In § 558.325 revise paragraph (e)(2)(xiv) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(2) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsors
*	*	* * *	*	*
(xiv) 100 to 200		For reduction in the severity of the effects of respiratory disease associated with *Mycoplasma hyopneumoniae*.	Feed as sole ration for 21 days	054771
*	*	* * *	*	*

* * * * *

Dated: March 29, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–06961 Filed 4–4–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 182

[Docket ID: DOD–2017–OS–0052]

RIN 0790–AK04

Defense Support of Civilian Law Enforcement Agencies

AGENCY: Under Secretary of Defense for Policy, DoD.

ACTION: Final rule.

SUMMARY: This final rule removes the Department of Defense (DoD) regulation concerning defense support of civilian law enforcement agencies. This part establishes DoD policy, assigns responsibilities, and provides procedures to key DoD individuals who provide support to Federal, State, Tribal, and local civilian law enforcement agencies within the United States, including the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and any territory or possession of the United