DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Changes of Sponsorship; Change of Sponsors' Names and Addresses

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 new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January, February, and March 2019. FDA is informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. Technical amendments are also being made to improve the accuracy, consistency, and readability of the regulations.

DATES: This rule is effective August 9, 2019, except for amendatory instructions 51 to 21 CFR 524.916 and 63 to 21 CFR 558.325, which are effective August 19, 2019, and instruction 60 to 21 CFR 558.235, which is effective September 9, 2019.

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 January, February, and March 2019, 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. 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 JANUARY, FEBRUARY, AND MARCH 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
January 27, 2019	009–476	Phibro Animal Health Corp., GlenPointe Centre East, 3d Floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.	NICARB 25% (nicarbazin) Type A medicated article.	Chickens	Supplemental approval of revised assay limits for nicarbazin (powder) Type A medicated article.	N/A.
January 28, 2019	200–616	Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland.	CEFENIL RTU (ceftiofur hydrochloride sterile suspension).	Swine and cattle	Original approval as a generic copy of NADA 140–890.	FOI Summary.
January 31, 2019	200–450	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin, 18, Ireland.	BIMECTIN PLUS (ivermectin/clorsulon) Injection for Cattle.	Cattle	Original approval as a generic copy of NADA 140–833.	FOI Summary.
February 4, 2019	200–637	Provetica AH LLC, 455 Sovereign Ct., Baldwin, MO 63011.	DOXIDYL (deracoxib) Chewable Tablet.	Dogs	Original approval as a generic copy of NADA 141–203.	FOI Summary.
February 8, 2019	141–297	Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002.	PROZINC (protamine zinc recombinant human insulin) Injectable Suspension.	Dogs	Supplemental approval for the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2019—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
March 29, 2019	048–761	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	AUREOMYCIN (chlortetracycline) Type C medicated feeds.	Cattle	Supplemental approval adding replacement dairy heifers to the indications for use of chlortetracycline Type C medicated cattle feeds for control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	N/A.
March 29, 2019	141–517	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	PROIN ER (phenylpropanolamine hydrochloride extended-release tablets) Tablets.	Dogs	Original approval for the control of urinary incontinence due to urethral sphincter hypotonus.	FOI Summary.

II. Changes of Sponsors' Names and Addresses

Aurora Pharmaceutical, LLC, 1196 Highway 3 South, Northfield, MN 55057–3009 has informed FDA that it has changed its name to Aurora Pharmaceutical, Inc.

Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002 has informed FDA that it has changed its name and address to Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.

Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967 has informed FDA that it has changed its name to American Regent, Inc.

Pharmgate LLC, 1800 Sir Tyler Dr., Wilmington, NC 28405 has informed FDA that it has changed its name to Pharmgate, Inc.

Accordingly, we are amending § 510.600(c) to reflect these changes.

III. Changes of Sponsorship

Provetica AH LLC, 455 Sovereign Ct., Baldwin, MO 63011 has informed FDA that it has transferred ownership of, and all rights and interest in, newly approved ANADA 200–637 for DOXIDYL (deracoxib) Chewable Tablets to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France. Following this change of sponsorship, Provetica AH LLC is no longer the sponsor of an approved application. Accordingly, it will not be added to the list of sponsors of approved applications in § 510.600(c) (21 CFR 510.600(c)).

Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096–4640 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096:

File No.	Proprietary name
006–623	CAPARSOLATE (arsenamide sodium) Injection.
008–422	SELEEN (selenium disulfide) Suspension.
010–424	NALLINE (nalorphine hydrochloride) Injection.
011–080	HYDELTRONE-TBA (prednisolone and tertiary butylacetate) Suspension.
011–437	HYDELTRONE (prednisolone sodium phosphate and neomycin sulfate) Ointment.
011–532	SULFABROM (sulfabromomethazine sodium) Bolus.
011–678	DIURIL (chlorothiazide) Tablets.
012–734	DIURIL (chlorothiazide) Bolus.
013–022	THIBENZOLE (thiabendazole) Sheep & Goat Wormer.
013–407	EQUIZOLE (thiabendazole) Horse Wormer.
013–674	HYDROZIDE (hydrochlorothiazide) Injection.
013–954	THIBENZOLE (thiabendazole) 20% Swine Premix.
014–350	OMNIZOLE (thiabendazole).
015–123	TBZ® (thiabendazole) Cattle Wormer (Drench).
015–875	TBZ 200 (thiabendazole) Medicated Premix.
030–103	THIBENZOLE (thiabendazole) Suspension.
034–114	EQUIZOLE (thiabendazole).
035–631	THIBENZOLE (thiabendazole) Pig Wormer.
037–410	EQUIZOLE A (thiabendazole and piperazine phosphate).
042–633	TRESADERM (thiabendazole, dexamethasone, neomycin sulfate solution) Dermatologic Solution.
043–141	THIBENZOLE 300 (thiabendazole) Medicated.
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets.
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Liquid.
048–487	TBZ (thiabendazole) Wormer Paste 50%.
042–633	TRESADERM (thiabendazole, dexamethasone, neomycin sulfate solution) Dermatologic Solution.
043–141	THIBENZOLE 300 (thiabendazole) Medicated.
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets.
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Liquid.
048–487	TBZ (thiabendazole) Wormer Paste 50%.
049–461	TBZ (thiabendazole) Wormer Paste 43%.
065–275	Penicillin VK Filmtab (penicillin V potassium) 250 mg.
065–276	VEESYN (penicillin V potassium) Granules for Oral Solution.
094–642	CAMVET (cambendazole) Suspension Horse Wormer.

File No.	Proprietary name
096–506	CAMVET (cambendazole) Horse Wormer Pellets.
096–731	CAMVET (cambendazole) Horse Wormer Paste 45%.
098–379	CYSTORELIN.
098–689	EQUIZOLE (thiabendazole) 50% Wormer Paste; EQUIZOLE 50% Wormer Paste for Horses.
127–443	EQVALAN (ivermectin) Injection.
128–409	IVOMEC (ivermectin) .27% Injection Grower and Feeder Pigs; IVOMEC (ivermectin) 1% Injection; IVOMEC (ivermectin) 1% Injection for Cattle and Swine; IVOMEC (ivermectin) Injection for Cattle.
131–392	IVOMEC (ivermectin) Liquid for Sheep.
134–314	EQVALAN (ivermectin).
134–930	SYNCRO-MATE-B (norgestomet and estradiol valerate) Implant.
136–742	CURATREM (clorsulon) Drench for Cattle.
137–006	IVOMEC (ivermectin) Cattle Paste 0.153%.
138–412	HEARTGARD (ivermectin) Tablets.
140–439	EQVALAN (ivermectin) Oral Liquid for Horses.
140–818	PRODUCIL (efrotomycin) Type A Medicated Article for Swine.
140–833	IVOMEC Plus (ivermectin and clorsulon) Injection For Cattle.
140–841	IVOMEC (ivermectin) Pour-On.
140–883	LEGEND (hyaluronate sodium) Injectable Solution.
140–886	HEARTGARD (ivermectin) Chewables for Dogs.
140–971	HEARTGARD Plus (ivermectin and pyrantel pamoate).
140–974	IVOMEC (ivermectin) Premix for Swine.
140–988	IVOMEC (ivermectin) Sustained-Release Bolus for Cattle.
141–015	ENACARD (enalapril maleate) Tablets for Dogs.
141–042	IMMITICIDE (melarsomine dihydrochloride) Sterile Powder.
141–054	IVOMEC (ivermectin) plus LINCOMIX (lincomycin).
141–078	HEARTGARD (ivermectin) for Cats.
141–079	EPRINEX (eprinomectin) Pour-On for Beef and Dairy Cattle.
141–097	BMD (bacitracin methylendisalicylate)/IVOMEC (ivermectin) Premix for Swine.
141–123	GASTROGARD (omeprazole).
141–188	MARQUIS (ponazuril) Antiprotozoal Oral Paste.
141–214	ZIMECTERIN Gold (ivermectin and praziquantel) Paste.
141–227	ULCERGARD (omeprazole).
141–230	PREVICOX (firocoxib) Chewable Tablets.
141–253	EQUIOXX (firocoxib) Oral Paste.
141–313	EQUIOXX (firocoxib) Injection.
141–327	LONGRANGE (eprinomectin) Injection.
141–328	ZACTRAN (gamithromycin) Injectable Solution.
141–406	NEXGARD (afoxolaner) Chewable Tablet.
141–421	DUOCARE (ivermectin and praziquantel) Paste.
141–458	EQUIOXX (firocoxib) Tablets.
141–492	CENTRAGARD (eprinomectin and praziquantel) Solution.
200–564	Ivermectin Paste 1.87%.

Following this change of sponsorship, Merial, Inc., is no longer the sponsor of an approved application. Accordingly, it will be removed from the list of sponsors of approved applications in § 510.600(c). As provided in the regulatory text, the animal drug regulations are amended to reflect these changes of sponsorship.

IV. Withdrawals of Approval

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096, has requested that FDA withdraw approval of newly transferred NADA 141–054 for use of LINCOMIX (lincomycin hydrochloride) plus IVOMEC (ivermectin) Type A medicated articles to manufacture 2-way, combination drug Type C medicated feed for swine because the product is no longer manufactured or marketed.

Also, Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 141–337 for use of RECOVYRA (fentanyl) Transdermal Solution for Dogs because the product is no longer manufactured or marketed.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 141–054 and 141–337, and all supplements and amendments thereto, is withdrawn effective August 19, 2019. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

V. Technical Amendments

FDA is removing ''IDEXX Pharmaceuticals, Inc.'' from the list of sponsors of approved applications in § 510.600(c). This action is being taken to improve the accuracy of the regulations.

In addition, we are reformatting the regulations to present the approved conditions of use of famphur, morantel, and thiabendazole in tabular format in the respective named sections of subpart B of part 558. This action is being taken to improve the readability and consistency of the regulations.

VI. 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 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, 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:
■ a. In the table in paragraph (c)(1):
■ i. Add an entry in alphabetical order for ''American Regent, Inc.'';
■ ii. Revise the entries for ''Aurora Pharmaceutical, LLC'', ''Boehringer Ingelheim Vetmedica, Inc.'';
■ iii. Remove the entries for ''IDEXX Pharmaceuticals, Inc.'', ''Luitpold Pharmaceuticals, Inc.'', and ''Merial, Inc.''; and
■ iv. Revise the entry for ''Pharmgate, LLC''; and
■ b. In the table in paragraph (c)(2):
■ i. Revise the entries for ''000010'' and ''010797'';
■ ii. Remove the entry for ''050604'';
■ iii. Revise the entry for ''051072'';
■ iv. Remove the entry for ''065274''; and
■ v. Revise the entry for ''069254''.

The additions and 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
* * * * * * *	
American Regent, Inc., Animal Health Division, Shirley, NY 11967	010797
* * * * * * *	
Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009	051072
* * * * * * *	
Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096	000010
* * * * * * *	
Pharmgate, Inc., 1800 Sir Tyler Dr., Wilmington, NC 28405	069254
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
000010	Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096.
* * * * * * *	
010797	American Regent, Inc., Animal Health Division, Shirley, NY 11967.
* * * * * * *	
051072	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.
* * * * * * *	
069254	Pharmgate, Inc., 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.

§ 520.43 [Amended]

■ 4. In § 520.43, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284a [Amended]

■ 5. In § 520.284a, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284b [Amended]

■ 6. In § 520.284b, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.284c [Amended]

■ 7. In § 520.284c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 8. Revise § 520.420 to read as follows:

§ 520.420 Chlorothiazide.

(a) *Specifications*—(1) Each tablet contains 0.25 grams chlorothiazide.

(2) Each bolus contains 2 grams chlorothiazide.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i)—*Amount.* Administer 5 to 10 milligrams per pound of body weight two or three times daily.

(ii) *Indications for use.* For treatment of congestive heart failure and renal edema.

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

(2) *Cows*—(i)—*Amount.* Administer 2 grams once or twice daily for 3 or 4 days.

(ii) *Indications for use.* As an aid in reduction of postparturient udder edema.

(iii) *Limitations.* Milk taken from dairy animals during treatment and for 72 hours (six milkings) after latest treatment must not be used for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.462 [Amended]

■ 9. In § 520.462, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.538 [Amended]

■ 10. In § 520.538, in paragraph (b), remove ''No. 058198'' and in its place add ''Nos. 013744 and 058198''.

§ 520.804 [Amended]

■ 11. In § 520.804, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.928 [Amended]

■ 12. In § 520.928, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.930 [Amended]

■ 13. In § 520.930, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1192 [Amended]

■ 14. In § 520.1192, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 520.1193 [Amended]

■ 15. In § 520.1193, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 520.1195 [Amended]

■ 16. In § 520.1195, in paragraph (b)(1), remove ''000859, 050604,'' and in its place add ''000010, 000859,''; and in paragraph (b)(3), remove ''050604'' and in its place add ''000010''.

§ 520.1196 [Amended]

■ 17. In § 520.1196, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1197 [Amended]

■ 18. In § 520.1197, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1198 [Amended]

■ 19. In § 520.1198, in paragraphs (b)(1) and (3), remove ''050604'' and in its place add ''000010''.

§ 520.1615 [Amended]

■ 20. In § 520.1615, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1696c [Amended]

■ 21. In § 520.1696c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.1696d [Amended]

■ 22. In § 520.1696d, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 23. In § 520.1760, revise paragraphs (a) and (c)(1) to read as follows:

§ 520.1760 Phenylpropanolamine.

(a) *Specifications*—(1) Each chewable tablet contains 25, 50, or 75 milligram (mg) phenylpropanolamine hydrochloride.

(2) Each extended-release tablet contains 18, 38, 74, or 145 mg phenylpropanolamine hydrochloride.

* * * * *

(c) * * *

(1) *Amount*—Administer orally as follows:

(i) Chewable tablet: 2 mg/kg of body weight twice daily.

(ii) Extended-release tablet: 2 to 4 mg/kg of body weight once daily with food.

* * * * *

§ 520.1855 [Amended]

■ 24. In § 520.1855, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2170 [Amended]

■ 25. In § 520.2170, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380a [Amended]

■ 26. In § 520.2380a, in paragraph (b)(2), remove ''050604'' and in its place add ''000010''.

§ 520.2380b [Amended]

■ 27. In § 520.2380b, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380c [Amended]

■ 28. In § 520.2380c, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 520.2380d [Amended]

■ 29. In § 520.2380d, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§§ 520.2380e and 520.2380f [Redesignated as §§ 520.2380f and 520.2380e]

■ 30. Redesignate §§ 520.2380e and 520.2380f as §§ 520.2380f and 520.2380e, respectively.

§ 520.2380e [Amended]

■ 31. In newly redesignated § 520.2380e, in paragraph (b), remove ''050604'' and in its place add ''000010''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.144 [Amended]

■ 33. In § 522.144, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 34. In § 522.313b, revise paragraphs (a), (b), and (e)(2)(iii) to read as follows:

§ 522.313b Ceftiofur hydrochloride.

(a) *Specifications.* Each milliliter of suspension contains:

(1) Ceftiofur hydrochloride equivalent to 50 milligrams (mg) of ceftiofur equivalents in the inactive vehicles phospholipan 90H, sorbitan monooleate, and cottonseed oil;

(2) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicle miglyol oil 812; or

(3) Ceftiofur hydrochloride equivalent to 50 mg ceftiofur equivalents in the inactive vehicles aluminum monostearate, sorbitan monooleate, and medium chain triglycerides.

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

(1) No. 054771 for products described in paragraphs (a)(1) and (2) of this section; and

(2) No. 055529 for the product described in paragraph (a)(3) of this section.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations*—(A) For products described in paragraphs (a)(2) and (3) of this section: Treated cattle must not be slaughtered for 3 days following the last treatment. For products described in paragraph (a)(2) of this section: Treated cattle must not be slaughtered for 4 days following the last treatment.

(B) A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

§ 522.814 [Amended]

■ 35. In § 522.814, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.850 [Amended]

■ 36. In § 522.850, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.930 [Amended]

■ 37. In § 522.930, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1014 [Amended]

■ 38. In § 522.1014, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1077 [Amended]

■ 39. In § 522.1077, in paragraph (b)(4), remove ''050604'' and in its place add ''000010''.

§ 522.1145 [Amended]

■ 40. In § 522.1145, in paragraph (e)(2)(i), remove ''050604'' and in its place add ''000010''.

§ 522.1150 [Amended]

■ 41. In § 522.1150, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 42. In § 522.1160, revise paragraphs (b)(1) and (2); redesignate the text of paragraph (c)(1)(i) as paragraph (c)(1)(i)(A); add a paragraph heading to newly redesignated paragraph (c)(1)(i)(A); and add paragraph (c)(1)(i)(B).

The revision and addition read as follows:

§ 522.1160 Insulin.

* * * * *

(b) * * *

(1) No. 000061 for use of product described in paragraph (a)(1) as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) as in paragraphs (c)(1)(i)(B), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) * * *

(1) * * *

(i) * * *

(A) *Porcine zinc insulin zinc.* * * *

(B) *Protamine zinc recombinant human insulin.* Administer a starting dose of 0.2 to 0.5 IU/pound of body weight (0.5 to 1.0 IU/kg) once daily. When transitioning from another insulin product, this form of insulin should be started once daily, regardless of the frequency of prior insulin use. The dose should be given concurrently with or right after a meal. Reevaluate the dog at appropriate intervals and adjust the dose based on both clinical signs and laboratory test results until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

* * * * *

§ 522.1192 [Amended]

■ 43. In § 522.1192, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

■ 44. In § 522.1193, revise paragraphs (b) and (e)(3) to read as follows:

§ 522.1193 Ivermectin and clorsulon.

* * * * *

(b) *Sponsors.* See Nos. 000010, 055529, 058005, and 061133 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(3) *Limitations*—(i) Nos. 000010 and 061133: Do not treat cattle within 21 days of slaughter. Nos. 055529 and 058005: Do not treat cattle within 49 days of slaughter.

(ii) Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

§ 522.1362 [Amended]

■ 45. In § 522.1362, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1452 [Amended]

■ 46. In § 522.1452, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 522.1885 [Amended]

■ 47. In § 522.1885, in paragraph (b), remove ''050604'' and in its place add ''000010''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.814 [Amended]

■ 49. In § 524.814, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.815 [Amended]

■ 50. In § 524.815, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.916 [Removed]

■ 51. Effective August 19, 2019, remove § 524.916.

§ 524.1193 [Amended]

■ 52. In § 524.1193, in paragraph (b)(1), remove ''050604'' and in its place add ''000010''.

§ 524.1484g [Amended]

■ 53. In § 524.1484g, in paragraph (b), remove ''026637 and 050604'' and in its place add ''000010 and 026637''.

§ 524.1484j [Amended]

■ 54. In § 524.1484j, in paragraph (b), remove ''050604'' and in its place add ''000010''.

§ 524.2101 [Amended]

■ 55. In § 524.2101, in paragraph (b), remove ''000061, 017135, and 050604'' and in its place add ''000010, 000061, and 017135''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.58 [Amended]

■ 57. In § 558.58, redesignate paragraphs (e)(3) through (6) as paragraphs (e)(2) through (5), and redesignate paragraph (e)(9) as new paragraph (e)(6).

§ 558.76 [Amended]

■ 58. In § 558.76, redesignate paragraphs (e)(1)(ix) through (xvi) as paragraphs (e)(1)(vii) through (xiv).

■ 59. In § 558.128, revise paragraphs (b)(1) and (e)(4)(xv), redesignate paragraphs (e)(4)(xvi) through (xxvi) as paragraphs (e)(4)(xvii) through (xxvii), and add new paragraph (e)(4)(xvi).

The revisions and addition read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(b) * * *

(1) *No. 054771:* 50, 70, 80, 90, or 100 grams per pound (g/lb) Type A medicated article.

* * * * *

(e) * * *

(4) * * *

Chlortetracycline amount	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xv) 350 mg/head/day.	.....	1. Beef cattle: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 hours prior to slaughter. To sponsor No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal period.	*
		2. Beef cattle (under 700 lb): For control of active infection of anaplasmosis caused by *A. marginale* susceptible to chlortetracycline.	To sponsor No. 054771 under NADAs 046–699 and 049–287, No. 066104 under NADA 092–286, and No. 069254 under NADA 048–480: Withdraw 48 h prior to slaughter. To sponsor No. 054771 under NADA 048–761 and No. 069254 under NADA 138–935 and ANADA 200–510: Zero withdrawal time.	*
(xvi) 20 to 350 g/ton.	.....	Beef cattle and replacement dairy heifers: For control of bacterial pneumonia associated with shipping fever complex caused by *Pasteurella* spp. susceptible to chlortetracycline.	Feed to provide chlortetracycline at the rate of 350 mg per head per day. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. To sponsor No. 054771 under NADA 048–761: Zero withdrawal period.	054771
*	*	*	*	*

* * * * *

§ 558.235 [Amended]

■ 60. Effective September 9, 2019, in § 558.235, in paragraph (b), remove ''050604'' and in its place add ''000010''.

■ 61. Revise § 558.254 to read as follows:

§ 558.254 Famphur.

(a) *Specifications.* Type A medicated articles containing 13.2 or 33.3 percent famphur.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.273 of this chapter.

(d) *Special considerations.* Famphur is a cholinesterase inhibitor. Do not use this product in animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals.

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

Famphur in grams/ton	Indications for use	Limitations	Sponsor
(i) 1.1 milligrams per pound (mg/lb) body weight per day.	Beef cattle and nonlactating dairy cows: 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
(ii) 2.3 mg/lb body weight per day.	Beef cattle and nonlactating dairy cows: 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

§ 558.300 [Amended]

■ 62. In § 558.300, in paragraph (b), remove ''050604'' and in its place add ''No. 000010''; in paragraphs (e)(1) through (6), in the ''Sponsor'' column, remove ''050604'' and in its place add ''000010''; and remove paragraph (f).

§ 558.325 [Amended]

■ 63. Effective August 19, 2019, in § 558.325, remove paragraphs (e)(2)(iii), (x), and (xvi); and redesignate paragraphs (e)(2)(iv) through (ix) as paragraphs (e)(2)(iii) through (viii), paragraphs (e)(2)(xi) through (xv) as paragraphs (e)(2)(ix) through (xiii), and paragraph (e)(2)(xvii) as paragraph (e)(2)(xiv).

■ 64. Revise § 558.360 to read as follows:

§ 558.360 Morantel.

(a) *Specifications.* Each pound of Type A medicated article contains 88 grams morantel tartrate.

(b) *Sponsor.* See No. 066104 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.425 of this chapter.

(d) *Special considerations*—(1) Do not use in Type B or Type C medicated feeds containing bentonite.

(2) Consult your veterinarian before using in severely debilitated animals and for assistance in the diagnosis, treatment, and control of parasitism.

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

Morantel tartrate in grams/ton	Indications for use	Limitations	Sponsor
(1) 0.44 to 4.4 grams of morantel tartrate per pound of feed.	Cattle: For removal and control of mature gastrointestinal nematode infections of cattle including stomach worms (*Haemonchus* spp., *Ostertagia* spp., *Trichostrongylus* spp.), worms of the small intestine (*Cooperia* spp., *Trichostrongylus* spp., *Nematodirus* spp.), and worms of the large intestine (*Oesophagostomum radiatum*).	Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat cattle within 14 days of slaughter.	066104
(2) 0.44 to 4.4 grams of morantel tartrate per pound of feed.	Goats: For removal and control of mature gastrointestinal nematode infections of goats including *Haemonchus contortus, Ostertagia (Teladorsagia) circumcincta,* and *Trichostrongylus axei.*	Feed as a single therapeutic treatment at 0.44 gram of morantel tartrate per 100 pounds of body weight. Fresh water should be available at all times. When medicated feed is consumed, resume normal feeding. Conditions of constant worm exposure may require retreatment in 2 to 4 weeks. Do not treat goats within 30 days of slaughter.	066104

■ 65. Revise § 558.600 to read as follows:

§ 558.600 Thiabendazole.

(a) *Specifications.* Dry Type A medicated articles containing 22, 44.1, 66.1, or 88.2 percent thiabendazole. The 66.1 percent Type A medicated article is solely for the manufacture of cane molasses liquid Type B feed, which is mixed in dry feeds. The 88.2 percent Type A medicated article is used solely for the manufacture of an aqueous slurry for adding to a Type C dry cattle feed.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) Special considerations. Do not use in Type B or Type C medicated feed containing bentonite.

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

(1) *Swine*—

Thiabendazole in grams/ton	Indications for use	Limitations	Sponsor
(i) 45.4 to 908 (0.005 to 0.1 percent).	Swine: As an aid in the prevention of infections of large roundworms (genus *Ascaris*).	Administer continuously in feed containing 0.05 to 0.1 percent thiabendazole per ton for 2 weeks followed by feed containing 0.005 to 0.02 percent thiabendazole per ton for 8 to 14 weeks. Do not treat animals within 30 days of slaughter.	000010
(ii) [Reserved]			

(2) *Cattle*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 3 grams per 100 lb. body weight.	For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*).	Use 3 grams per 100 lb. body weight at a single dose; may repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	000010
(ii) 5 grams per 100 lb. body weight.	For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Nematodirus spp., Oesophagostomum radiatum*); control of infections of *Cooperia spp.*	Use 5 grams per 100 lb. body weight at a single dose or divided into 3 equal doses, administered 1 dose each day, on succeeding days. May repeat once in 2 to 3 weeks. Do not treat animals within 3 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	000010

(3) *Minor species*—

Thiabendazole amount	Indications for use	Limitations	Sponsor
(i) 2 grams per 100 lb. body weight.	Sheep and goats: For control of infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp.; Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*); also active against ova and larvae passed by sheep from 3 hours to 3 days after the feed is consumed (good activity against ova and larvae of *T. colubriformis* and *axei, Ostertagia spp., Nematodirus spp., Strongyloides spp.;* less effective against those of *Haemonchus contortus* and *Oesophagostomum spp.*).	Use 2 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(ii) 3 grams per 100 lb. body weight.	Goats: For control of severe infections of gastrointestinal roundworms (*Trichostrongylus spp., Haemonchus spp., Ostertagia spp., Cooperia spp., Nematodirus spp., Bunostomum spp., Strongyloides spp., Chabertia spp.,* and *Oesophagostomum spp.*).	Use 3 grams per 100 lb. body weight at a single dose. Do not treat animals within 30 days of slaughter. Milk taken from treated animals within 96 hours (8 milkings) after the latest treatment must not be used for food.	050604
(iii) 454 grams per ton of feed.	Pheasants: For the treatment of gapeworms (*Syngamus trachea*).	Feed continuously for 2 weeks (14 days). Do not use treated pheasants for food for 21 days after last day of treatment. Fertility, hatchability, and other reproductive data are not available on use in breeding animals.	050604

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16884 Filed 8–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 524 and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) at the sponsors' request because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective August 19, 2019.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Animal Health USA Inc., 3239 Satellite Blvd., Duluth, GA 30096, has requested that FDA withdraw approval of NADA 141–054 for use of LINCOMIX (lincomycin hydrochloride) and IVOMEC (ivermectin) Type A medicated articles in the manufacture of 2-way, combination drug Type C medicated swine feeds because the product is no longer manufactured or marketed.

Also, Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 141–337 for use of RECOVYRA (fentanyl) Transdermal Solution for Dogs because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADAs 141–054 and NADA 141–337, and all supplements and amendments thereto, is hereby withdrawn, effective August 19, 2019.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: August 1, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–16885 Filed 8–8–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2019–0673]

Special Local Regulations; Annual Les Cheneaux Islands Antique Wooden Boat Show; Hessel, MI.

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a special local regulation for the Annual Les Cheneaux Islands Antique Wooden Boat Show on August 10, 2019, from 7 a.m. to 6:30 p.m. to provide for the safety of life on navigable waterways during this event. During the enforcement period, all vessels will operate at a no wake speed and follow the directions of the on-scene Patrol Commander.

DATES: The regulations in 33 CFR 100.922 will be enforced on August 10, 2019, from 7 a.m. to 6:30 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email LT Sean Murphy, Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *Sean.V.Murphy@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulation in 33 CFR 100.922 for the Annual Les Cheneaux Islands Antique Wooden Boat Show on August 10, 2019