PART 1—GENERAL ENFORCEMENT REGULATIONS

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

Authority: 15 U.S.C. 1333, 1453, 1454, 1455, 4402; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 342i, 343, 350c, 350d, 350e, 352, 355, 360b, 360ccc, 360ccc–1, 360ccc–2, 362, 371, 373, 374, 381, 382, 387, 387a, 387c, 393; 42 U.S.C. 216, 241, 243, 262, 264.

§ 1.1 [Amended]

■ 2. Amend § 1.1(c) as follows:
■ a. Remove ''101.105(f)'' and add in its place ''101.7(f)''.
■ b. Remove ''101.105(i)'' and add in its place ''101.7(i)''.
■ c. Remove ''101.105(j)'' and add in its place ''101.7(j)''.
■ d. Remove ''101.105(o)'' and add in its place ''101.7(o)''.

§ 1.20 [Amended]

■ 3. In § 1.20, by removing ''§ 101.105(f)'' and adding in its place ''§ 101.7(f)''.

§ 1.24 [Amended]

■ 4. Amend § 1.24 as follows:
■ a. Remove ''§ 101.105'' in paragraph (a)(2) and add in its place ''§ 101.7''.
■ b. Remove ''§ 101.105(b)(2)'' wherever it appears and add in its place ''§ 101.7(b)(2)''.
■ c. Remove ''§ 101.105(f)'' wherever it appears and add in its place ''§ 101.7(f)''.
■ d. Remove ''§ 101.105(j)'' wherever it appears and add in its place ''§ 101.7(j)''.
■ e. Remove ''§ 101.105(j)(1)'' wherever it appears and add in its place ''§ 101.7(j)(1)''.

PART 100—GENERAL

■ 5. The authority citation for part 100 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 337, 342, 343, 348, 371.

§ 100.155 [Amended]

■ 6. Amend § 100.155 in paragraphs (a) and (b) by removing ''§ 101.105'' and adding in its place ''§ 101.7''.

PART 101—FOOD LABELING

■ 7. The authority citation for part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

§ 101.2 [Amended]

■ 8. Amend § 101.2 in paragraph (c) introductory text by removing ''§ 101.105(h)(1)'' and adding in its place ''§ 101.7(h)(1)''.

§ 101.105 [Redesignated as § 101.7]

■ 9. Redesignate § 101.105 as § 101.7.
■ 10. Revise newly designated § 101.7 section heading to read as follows:

§ 101.7 Declaration of net quantity of contents.

* * * * *

§ 101.13 [Amended]

■ 11. Amend paragraphs (d)(2), (h)(4)(i), and (i)(2) by removing ''§ 101.105(i)'' and adding in its place ''§ 101.7(i)''.

§ 101.30 [Amended]

■ 12. Amend § 101.30(g) by removing ''§ 101.105(i)'' and adding in its place ''§ 101.7(i)''.

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

■ 13. The authority citation for part 104 continues to read as follows:

Authority: 21 U.S.C. 321, 343, 371(a).

§ 104.5 [Amended]

■ 14. Amend § 104.5(b) by removing ''§ 101.105'' and adding in its place ''§ 101.7''.

Dated: August 16, 2016.

Jeremy Sharp,

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

[FR Doc. 2016–19925 Filed 8–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2016–N–0002]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 May and June 2016. 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 changes of sponsorship of applications, changes of sponsors' names and addresses, and the voluntary withdrawals of approval of applications.

DATES: This rule is effective August 29, 2016, except for the amendments to 21 CFR 558.274, 58.355, 58.363, 58.550, 558.625, and 558.630, which are effective September 8, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 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 May and June 2016, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY AND JUNE 2016

Approval date	File No.	Sponsor	Product name	Species	Indications for use/effect of the action	Public documents
May 2, 2016	141–439	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	INTEPRITY (avilamycin) Type A medicated article.	Chickens	Original approval for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.	FOI Summary, EA/FONSI.[1]
May 16, 2016	141–457	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	ENTYCE (capromorelin oral solution).	Dogs	Original approval for appetite stimulation in dogs.	FOI Summary.
May 17, 2016	141–463	Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140.	ONSIOR (robenacoxib) Tablets for Dogs.	Dogs	Original approval for the control of postoperative pain and inflammation associated with soft tissue surgery in dogs.	FOI Summary.
May 17, 2016	200–536	Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861.	MOMETAVET (gentamicin sulfate, USP; mometasone furoate anhydrous, USP; and clotrimazole, USP) Otic Suspension.	Dogs	Original approval of a generic copy of NADA 141–177.	FOI Summary.
May 24, 2016	200–596	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	TILMOVET 90 (tilmicosin phosphate) and RUMENSIN 90 (monensin) Type A medicated articles.	Cattle	Original approval for use in two-way, combination drug Type B and Type C medicated feeds for cattle fed in confinement for slaughter.	FOI Summary.
June 20, 2016	200–587	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland.	FERROFORTE (gleptoferron injection).	Piglets	Original approval as a generic copy of NADA 110–399.	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. Changes of Sponsorship

Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma EOOD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product name	21 CFR section
200–228	PHOENECTIN (ivermectin) Injectable Solution	522.1192
200–254	Iron Dextran Injection, 100 mg/mL	522.1182
200–256	Iron Dextran Injection, 200 mg/mL	522.1182
200–351	Lincomycin Injectable, USP	522.1260
200–389	Amprolium 9.6% Oral Solution	520.100

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

III. Withdrawals of Approval

In addition, during May and June 2016, Elanco US, Inc., 2500 Innovation Way, Greenfield, IN 46140 requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
012–548 [1]	TYLOSIN (tylosin phosphate)/HYGROMIX (hygromycin B)	558.274
013–162 [1]	TYLAN TM (tylosin phosphate) Type A medicated article	558.625
013–388 [1]	TYLAN (tylosin phosphate)/HYGROMIX (hygromycin B) Premix	558.274
015–166 [1]	TYLAN TM (tylosin phosphate) Type A medicated article	558.625
127–507 [1]	TYLAN 5, 10, 20, or 40 SULFA-G (tylosin phosphate and sulfamethazine)	558.630
141–164 [1]	TYLAN (tylosin phosphate)/COBAN (monensin)	558.355
141–170 [1]	TYLAN (tylosin phosphate)/MONTEBAN (narasin)	558.363
141–198 [1]	TYLAN TM (tylosin phosphate)/BIO-COX (salinomycin)	558.550

[1] These NADAs were identified as being affected by guidance for industry #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 012–548, 013–162, 013–388, 015–166, 127–507, 141–640, 141–170, and 141–198, and all supplements and amendments thereto, is withdrawn, effective September 8, 2016. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

IV. Technical Amendments

FDA has noticed that a drug labeler code in 21 CFR 520.2325a does not accurately reflect the sponsorship of a new animal drug application. At this time, we are amending this section. This action is being taken to improve the accuracy of the regulations.

Also, ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105 has informed FDA that it is changing its name and address to Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138.

Alexion Pharmaceuticals, Inc., 33 Hayden Ave., Lexington, MA 02421 has informed FDA that it has changed its address to 100 College St., New Haven, CT 06510. At this time, this firm is being added to the list of sponsors of approved application in 21 CFR 510.600(c) which we had not done previously.

FDA has noticed that the maximum concentration of sulfadimethoxine with ormetoprim in 2-way, fixed-ratio combination drug Type B medicated feeds in 21 CFR 558.4 was amended in error. At this time, we are revising this section to provide for appropriate concentrations in Type B medicated feeds for salmonids and catfish. This action is being taken to improve the accuracy of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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), alphabetically add an entry for ''Alexion Pharmaceuticals, Inc.'', remove the entry for ''ConAgra Pet Products Co.'', and alphabetically add an entry for ''Sergeant's Pet Care Products, Inc.''; and in the table in paragraph (c)(2), revise the entry for ''021091'' and numerically add an entry for ''069334''.

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
* * * * * * *	
Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510	069334
* * * * * * *	
Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138	021091
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
021091	Sergeant's Pet Care Products, Inc., 10077 S. 134th St., Omaha, NE 68138.
* * * * * * *	
069334	Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510.
* * * * * * *	

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.

§ 520.100 [Amended]

■ 4. In § 520.100, remove paragraphs (b)(3) and (4).

§§ 520.300, 520.300a, 520.300b, and 520.300c [Redesignated as §§ 520.284, 520.284a, 520.284b, and 520.284c.]

■ 5. Redesignate §§ 520.300, 520.300a, 520.300b, and 520.300c as §§ 520.284, 520.284a, 520.284b, and 520.284c.

■ 6. Add § 520.292 to read as follows:

§ 520.292 Capromorelin.

(a) *Specifications.* Each milliliter of solution contains 30 milligrams (mg) capromorelin.

(b) *Sponsor.* See No. 086026 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 3 mg/kg once daily by mouth.

(2) *Indications for use.* For appetite stimulation in dogs.

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

■ 7. In § 520.2075, revise paragraphs (a) and (c) to read as follows:

§ 520.2075 Robenacoxib.

(a) *Specifications.* Each tablet contains 10, 20, or 40 milligrams (mg) robenacoxib for use in dogs, or 6 mg robenacoxib for use in cats.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer 0.91 mg/lb (2 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with soft tissue surgery in dogs weighing at least 5.5 lb (2.5 kg) and at least 4 months of age for a maximum of 3 days.

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

(2) *Cats*—(i) *Amount.* Administer 0.45 mg/lb (1 mg/kg) orally, once daily, for a maximum of 3 days.

(ii) *Indications for use.* For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats weighing at least 5.5 lb (2.5 kg) and at least 4 months of age for a maximum of 3 days.

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

§ 520.2325a [Amended]

■ 8. In § 520.2325a, in paragraph (a)(3), remove ''053501'' and in its place add ''054771''.

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. Revise § 522.1055 to read as follows:

§ 522.1055 Gleptoferron.

(a) *Specifications.* Each milliliter (mL) contains the equivalent of 200 milligrams of elemental iron as gleptoferron, a complex of ferric hydroxide and dextran glucoheptonic acid.

(b) *Sponsors.* See Nos. 059120 and 061623 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) *Indications for use and amounts*—(i) Prevention of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection on or before 3 days of age.

(ii) Treatment of anemia due to iron deficiency: Administer 1 mL (200 mg iron) per pig by intramuscular injection as soon as signs of deficiency appear.

(2) [Reserved]

§ 522.1182 [Amended]

■ 11. In § 522.1182, in paragraph (b) introductory text, remove ''baby pigs'' and in its place add ''young piglets''; in paragraph (b)(7) introductory text, remove ''000859'' and in its place add ''016592''; and in paragraphs (b)(7)(i) and (ii), remove ''baby pig''.

§ 522.1192 [Amended]

■ 12. In § 522.1192, in paragraph (b)(2), remove ''000859'' and in its place add ''016592,''.

§ 522.1260 [Amended]

■ 13. In § 522.1260, in paragraph (b)(2), remove ''000859'' and in its place add ''016592''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 15. In § 524.1044h, revise paragraphs (a) and (b) to read as follows:

§ 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

(a) *Specifications.* Each gram of suspension contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate or mometasone furoate anhydrous, USP, equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsors.* See Nos. 000061 and 054925 in § 510.600(c) of this chapter.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

■ 17. In § 558.4, in paragraph (d), in the ''Category I'' table, in the ''Type B maximum (200 ×)'' column, in the row entry for ''Avilamycin'', remove ''3.65 g/lb (0.8%)'' and in its place add ''7.3 g/lb (1.6%)''; and in the ''Category II'' table, remove the row entry for ''Sulfadimethoxine'' and two following row entries for ''Ormetoprim'', and in their place add row entries for ''Sulfadimethoxine'' and ''Ormetoprim''.

The additions read as follows:

§ 558.4 Requirement of a medicated feed mill license.

* * * * *

(d) * * *

CATEGORY II

Drug	Assay limits percent [1] Type A	Type B maximum (100 ×)	Assay limits percent Type B/C
* * *	*	* * *	*
Sulfadimethoxine	90–110	Poultry: 5.675 g/lb Fish: 85.1 g/lb	80–115/75–125
Ormetoprim	90–110	Poultry: 3.405 g/lb Fish: 17.0 g/lb	80–115
* * *	*	* * *	*

* * * * *

■ 18. In § 558.68, revise paragraphs (a) and (e) to read as follows:

§ 558.68 Avilamycin.

(a) Each pound of Type A medicated article contains 45.4 or 90.7 grams of avilamycin.

* * * * *

(e) *Conditions of use.* Administer in feed as follows:

(1) *Chickens*—

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 13.6 to 40.9		Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age.	000986
(ii) [Reserved].				

(2) *Swine*—

Avilamycin in grams/ton	Combinationin grams/ton	Indications for use	Limitations	Sponsor
(i) 73		Weaned pigs less than 14 weeks of age: For the reduction in incidence and overall severity of diarrhea in the presence of pathogenic *Escherichia coli* in groups of weaned pigs.	Feed as the sole ration for 21 consecutive days. To assure responsible antimicrobial drug use in pigs, do not administer to pigs 14 weeks of age or older.	000986
(ii) [Reserved].				

§ 558.274 [Amended]

■ 19. Effective September 8, 2016, in § 558.274, remove and reserve paragraphs (c)(1)(ii) and (c)(2)(ii).

■ 20. Effective September 8, 2016, in § 558.355, remove and reserve paragraph (f)(1)(xxviii) and revise paragraphs (f)(8)(i) and (ii).

The revisions read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(8) * * *

(i) Decoquinate alone and in combination as in § 558.195.

(ii) Melengestrol acetate alone and in combination as in § 558.342.

* * * * *

§ 558.363 [Amended]

■ 21. Effective September 8, 2016, in § 558.363, remove and reserve paragraph (d)(1)(vi).

§ 558.550 [Amended]

■ 22. Effective September 8, 2016, in § 558.550, remove and reserve paragraph (d)(1)(xxii).

§ 558.618 [Amended]

■ 23. In § 558.618, in paragraphs (e)(2)(ii) and (iii):

■ a. In the ''Limitations'' column, add ''Tilmicosin as provided by Nos. 000986 or 016952; monensin as provided by No. 000986 in § 510.600(c) of this chapter.'' to the end of the existing entries; and

■ b. In the ''Sponsor'' column, numerically add ''016952''.

■ 24. Effective September 8, 2016, in § 558.625, revise paragraphs (b)(1), (f)(2)(i), (f)(2)(iii), and (f)(2)(vii) and remove paragraphs (f)(2)(viii) and (ix).

The revisions read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(1) No. 000986: 40 and 100 grams per pound for use as in paragraph (f) of this section.

* * * * *

(f) * * *

(2) * * *

(i) Decoquinate alone and in combination as in § 558.195.

* * * * *

(iii) Melengestrol acetate alone and in combination as in § 558.342.

* * * * *

(vii) Zilpaterol alone and in combination as in § 558.665.

■ 25. Effective September 8, 2016, in § 558.630, revise paragraph (b)(1) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

* * * * *

(b) * * *

(1) No. 000986: 40 and 100 grams per pound for use as in paragraph (e) of this section.

* * * * *

Dated: August 8, 2016.

Tracey H. Forfa,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016–19914 Filed 8–26–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs for Use in Animal Feed; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

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

DATES: Withdrawal of approval is effective September 8, 2016.

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: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
012–548 [1]	TYLOSIN (tylosin phosphate)/HYGROMIX (hygromycin B)	558.274
013–162 [1]	TYLAN TM (tylosin phosphate) Type A medicated article	558.625