Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222, as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to or be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). If this rule were delayed to allow for notice and comment and a delay in effective date, then the national security and foreign policy objectives of this rule would be harmed. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

List of Subject in 15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

Accordingly, part 744 of the Export Administration Regulations (15 CFR parts 730 through 774) is amended as follows:

PART 744—[AMENDED]

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 20, 2016, 81 FR 3937 (January 22, 2016); Notice of August 4, 2016, 81 FR 52587 (August 8, 2016); Notice of September 15, 2016, 81 FR 64343 (September 19, 2016); Notice of November 8, 2016, 81 FR 79379 (November 10, 2016).

Supplement No. 7 to Part 744—[AMENDED]

■ 2. In Supplement No. 7 to part 744, remove ''February 27, 2017'' and add in its place ''March 29, 2017''.

Dated: February 21, 2017.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2017–03664 Filed 2–23–17; 8:45 am]

BILLING CODE 3510–33–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 a New Animal Drug Application; Change of Sponsor; 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 September and October 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 several applications and a change of a sponsor's address.

DATES: This rule is effective February 24, 2017, except for the amendment to 21 CFR 524.1465, which is effective March 6, 2017.

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 September and October 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 SEPTEMBER AND OCTOBER 2016

Approval date	File No.	Sponsor	Product name	Species	Effect of the action/indications for use	Public documents
October 26, 2016	141–465	Elanco US Inc, 2500 Innovation Way, Greenfield, IN 46140.	INTEPRITY (avilamycin) and COBAN (monensin) Type C medicated feeds.	Chickens	Original approval for the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens; and as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*.	FOI Summary.
September 8, 2016	200–592	Putney, Inc., One Monument Sq., Suite 400, Portland, ME 04101.	Amoxicillin Trihydrate and Clavulanate Potassium Tablets.	Dogs	Original approval of a generic copy of NADA 055–099.	FOI Summary.

II. Change of Sponsorship

Sogeval S. A., 200 Avenue de Mayenne, 53000 Laval, France has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France:

File No.	Product name	21 CFR section
099–667	IMPOSIL (iron heptomer) Injection	522.1182
110–399	GLEPTOSIL (gleptoferron) Injection	522.1055

Following these changes of sponsorship, Sogeval S. A. is no longer the sponsor of an approved NADA. Accordingly, the firm's name, address, and drug labeler code are being removed from § 510.600(c) (21 CFR 510.600(c)).

In addition, Zoetis, Inc., 333 Portage St., Kalamazoo, MI 49007 has informed FDA that it has transferred ownership of, and all rights and interest in, the following applications to Kinetic Technologies, LLC, 961 Beasley St., Suite 270, Lexington, KY 40509:

File No.	Product name	21 CFR section
006–417	RECOVR (tripelennamine hydrochloride) Injection	522.2615
032–319	FUROX (furazolidone) Aerosol Powder	524.1005
038–838	ROBAXIN–V (methocarbamol) Injection	522.1380
108–687	PET DERM III (dexamethasone) Tablets	520.540c
111–369	Dexamethasone Sterile Solution	522.540

Following these changes of sponsorship, Kinetic Technologies, LLC is now the sponsor of an approved NADA. Accordingly, the firm's name, address, and drug labeler code are being added to § 510.600(c).

III. Withdrawals of Approval

In addition, Putney, Inc., One Monument Square, Suite 400, Portland, ME 04101 has requested that FDA withdraw approval of ANADA 200–524 for Mupirocin Ointment 2% because the product is no longer manufactured or marketed.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of ANADA 200–524, and all supplements and amendments thereto, is withdrawn, effective March 6, 2017.

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect this voluntary withdrawal of approval.

IV. Technical Amendments

Wildlife Laboratories, Inc., 1401 Duff Dr., Suite 600, Fort Collins, CO 80524 has informed FDA that it has changed its address to 1230 W. Ash St., Suite D, Windsor, CO 80550. In addition, FDA has noticed that a sponsor name in § 510.600 does not reflect the particular punctuation used in this sponsor's applications and other correspondence. At this time, we are amending the list of sponsors of approved applications in § 510.600(c) to reflect this change of sponsor address and sponsor's punctuation.

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.

§ 510.600 [Amended]

■ 2. Revise § 510.600 as follows:
■ a. In the table in paragraph (c)(1):
■ i. In the entry for ''Elanco US, Inc.'', remove ''Elanco US, Inc.'' and in its place add ''Elanco US Inc.'';
■ ii. Alphabetically add an entry for ''Kinetic Technologies, LLC'';
■ iii. Remove the entry for ''Sogeval S. A.''; and
■ iv. Revise the entry for ''Wildlife Laboratories, Inc.''
■ b. In the table in paragraph (c)(2):
■ i. Numerically add an entry for ''051031'';
■ ii. Revise the entry for ''053923''
■ iii. In the entry for ''058198'', remove ''Elanco US, Inc.'' and in its place add ''Elanco US Inc.''; and
■ iv. Remove the entry for ''059120''.

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
* * * * * * *	
Kinetic Technologies, LLC, 961 Beasley St., Suite 270, Lexington, KY 40509	051031
* * * * * * *	
Wildlife Laboratories, Inc., 1230 W. Ash St., Suite D, Windsor, CO 80550	053923
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
051031	Kinetic Technologies, LLC, 961 Beasley St., Suite 270, Lexington, KY 40509.
* * * * * * *	
053923	Wildlife Laboratories, Inc., 1230 W. Ash St., Suite D, Windsor, CO 80550.
* * * * * * *	

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 paragraph (b), remove ''No. 054771'' and in its place add ''Nos. 026637 and 054771''.

§ 520.540c [Amended]

■ 5. In § 520.540c, in paragraph (b), remove ''054771'' and in its place add ''051031''.

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.

§ 522.540 [Amended]

■ 7. In § 522.540, in paragraph (d)(2)(i), remove ''054771'' and in its place add ''051031''.

§ 522.1055 [Amended]

■ 8. In § 522.1055, in paragraph (b), remove ''059120'' and in its place add ''013744''.

§ 522.1182 [Amended]

■ 9. In § 522.1182, in paragraph (b)(3), remove ''059120'' and in its place add ''013744''.

§ 522.1380 [Amended]

■ 10. In § 522.1380, in paragraph (b), remove ''054771'' and in its place add ''051031''.

§ 522.2615 [Amended]

■ 11. In § 522.2615, in paragraph (b), remove ''054771'' and in its place add ''051031''.

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.

§ 524.1005 [Amended]

■ 13. In § 524.1005, in paragraph (b)(1), remove ''054771'' and in its place add ''051031''.

§ 524.1465 [Amended]

■ 14. Effective March 6, 2017, in § 524.1465, in paragraph (b), remove ''026637''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 16. In § 558.68, revise paragraph (e)(1)(ii) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(e) * * *

(1) * * *

Avilamycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 13.6 to 40.9	Monensin 90 to 110; as provided by No. 058198 in § 510.600(c) of this chapter.	Broiler chickens: For the prevention of mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens; and as an aid in 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 assure responsible antimicrobial drug use in broiler chickens, treatment administration must begin on or before 10 days of age. See § 558.355(d) of this chapter for additional required labeling.	058198

* * * * *

Dated: February 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03677 Filed 2–23–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

[Docket No. FDA–2016–N–0002]

New Animal Drugs; 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 an abbreviated new animal drug application (ANADA) at the sponsor's request because the product is no longer manufactured or marketed.

DATES: Withdrawal of approval is effective March 6, 2017.

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: Putney, Inc., One Monument Square, Suite 400, Portland, ME 04101 has requested that FDA withdraw approval of ANADA 200–524 for Mupirocin Ointment 2% because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of ANADA 200–524, and all supplements and amendments thereto, is hereby withdrawn, effective March 6, 2017.

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

Dated: February 21, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03678 Filed 2–23–17; 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; 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 18 new animal drug applications (NADAs) and 2 abbreviated new animal drug applications (ANADAs). These withdrawals of approval of NADAs and ANADAs for antimicrobial drugs of importance to human medicine that are administered to food-producing animals in medicated feed are being made because the products are no longer manufactured or marketed. These actions are consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

DATES: Withdrawal of approval is effective February 24, 2017.

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: FDA is withdrawing approval of 18 NADAs and 2 ANADAs. These applications were identified as being affected by guidance for industry (GFI) #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 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*). Their withdrawal of approval is consistent with the FDA Center for Veterinary Medicine's initiative for the Judicious Use of Antimicrobials.

Approval of the following applications for new animal drugs administered in medicated feed is being voluntarily withdrawn at the sponsors' requests because these products are no longer manufactured or marketed:

File No.	Product name	Sponsor
044–820	LINCOMIX (lincomycin)/AMPROL PLUS (amprolium and ethopabate).	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007 (Zoetis Inc.).