15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 736

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, parts 730, 734, 736, 742, 744, and 745 of the EAR (15 CFR parts 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; 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. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; 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; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 734—[AMENDED]

■ 2. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 736—[AMENDED]

■ 3. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of May 6, 2015, 80 FR 26815 (May 8, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 742—[AMENDED]

■ 4. The authority citation for 15 CFR part 742 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *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; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; 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. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 744—[AMENDED]

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *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 21, 2015, 80 FR 3461 (January 22, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 745—[AMENDED]

■ 6. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

Dated: November 30, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–30753 Filed 12–8–15; 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–2015–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawals of Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) 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 2015. 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 and the voluntary withdrawals of approval of applications that occurred in September and October 2015.

DATES: This rule is effective December 9, 2015, except for the amendments to 21 CFR 520.446, 520.2043, 558.625, and 558.630, which are effective December 21, 2015.

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 2015, 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 Center for Veterinary Medicine 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 2015

File No.	Sponsor	Product name	Action	21 CFR section	FOIA summary	NEPA review
141–440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410.	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution.	Original approval for the treatment of otitis externa in dogs.	524.957	yes	CE.[1] [2]
141–449	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate.	Original approval for the treatment and control of certain nematode worms in broiler chickens, replacement chickens intended to become breeding chickens, and breeding chickens.	520.905a	yes	EA/FONSI.[3]
141–442	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LUTALYSE HighCon (dinoprost tromethamine injection) Injection.	Supplemental approval of subcutaneous route of administration.	522.690	yes	CE.[1] [4]
108–901	Zoetis Inc. 333 Portage St., Kalamazoo, MI 49007.	LUTALYSE (dinoprost tromethamine injection) Injection.	Supplemental approval of revised indications for uses in cattle.	522.690	no	CE.[1] [4]

[1] The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.
[2] CE granted under 21 CFR 25.33(d)(1).
[3] 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).
[4] CE granted under 21 CFR 25.33(a)(1).

II. Changes of Sponsorship

During September and October 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

File No.	Previous sponsor	Product name	New sponsor	21 CFR section
141–440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410.	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution.	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	524.957
200–582	Orkeo USA, Inc., 77 Water St., New York, NY 10005.	LONCOR 300 (florfenicol) Injectable Solution.	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	522.955

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship. Following the change of sponsorship of ANADA 200–582, Orkeo USA, Inc., is no longer the sponsor of an approved application.

III. Withdrawals of Approval

In addition, during September and October 2015, the following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
140–680 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN (tylosin phosphate) Premix	558.625

File No.	Sponsor	Product name	21 CFR section
140–681 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix.	558.630
200–028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200–383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CLINDAROBE (clindamycin) Capsules	520.446

[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 NADA 140–680, NADA 140–681, ANADA 200–028, and ANADA 200–383, and all supplements and amendments thereto, is withdrawn, effective December 21, 2015. 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 previous sponsor of ANADA 200–383, Teva Canada Ltd., was no longer the sponsor of an approved application following a prior change of sponsorship. At this time, FDA is amending the regulation to remove the firm from the listings of sponsors of approved applications in 21 CFR 510.600. This action is being taken to improve the accuracy of the regulations.

FDA is also revising the special considerations for medicated feeds containing veterinary feed directive drugs to align with 21 CFR 558.6(a)(6), which was recently amended (80 FR 31708, June 3, 2015). This action is being taken to improve the consistency 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 21 CFR part 510 continues to read as follows:

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

§ 510.600 [Amended]

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), remove the entries for ''Orkeo USA, Inc.'' and ''Teva Canada Ltd.''; and

■ b. In the table in paragraph (c)(2), remove the entries for ''043806'' and ''086050''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.446 [Amended]

■ 4. Effective December 21, 2015, in § 520.446, in paragraph (b)(1), remove ''Nos. 000859 and 054771'' and in its place add ''No. 054771''.

■ 5. In § 520.905a:

■ a. Revise paragraphs (a) and (e)(4)(i);

■ b. In paragraph (e)(4)(iii), remove the first sentence; and

■ c. Add paragraph (e)(5).

The revisions and addition read as follows:

§ 520.905a Fenbendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) fenbendazole for use as in paragraphs (e)(1), (2), (3), and (4) of this section; or 200 mg fenbendazole for use as in paragraph (e)(5) of this section.

* * * * *

(e) * * *

(4) * * *

(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

* * * * *

(5) *Chickens*—(i) *Amount.* Administer orally via drinking water at a daily dose of 1 mg/kg body weight (0.454 mg/lb) for 5 consecutive days.

(ii) *Indications for use.* For the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens intended to become breeding chickens, and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens.

(iii) *Limitations.* Not for use in laying hens and replacement chickens intended to become laying hens.

§ 520.2043 [Amended]

■ 6. Effective December 21, 2015, in § 520.2043, in paragraph (b)(2), remove ''Nos. 054771, 055246, 058829, and 059130'' and in its place add ''Nos. 000859, 054771, and 058829''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 8. In § 522.690, revise paragraphs (b)(2) and (d)(1)(i) and add paragraph (b)(3) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(b) * * *

(2) No. 054771 for use of the 5 mg/mL product as in paragraphs (d)(1), (2), and (3) of this section.

(3) No. 000859 for use of the 5 mg/mL product as in paragraphs (d)(2), (3), and (4) of this section.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 25 mg as a single intramuscular or subcutaneous injection.

* * * * *

§ 522.955 [Amended]

■ 9. In § 522.955(b)(2), remove ''086050'' and in its place add ''000859''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 11. Add § 524.957 to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications.* Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 15 milligrams (mg) florfenicol, 13.3 mg terbinafine, and 2 mg mometasone furoate.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dropperette (1 mL) per affected ear(s).

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 12. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 13. In § 558.68, revise paragraph (c)(1) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

■ 14. In § 558.261, revise paragraphs (c)(1) and (2) introductory text to read as follows:

§ 558.261 Florfenicol.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

* * * * *

■ 15. In § 558.618, revise paragraph (c)(1) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

§ 558.625 [Amended]

■ 16. Effective December 21, 2015, in § 558.625, remove paragraph (b)(5) and redesignate paragraph (b)(6) as paragraph (b)(5).

§ 558.630 [Amended]

■ 17. Effective December 21, 2015, in § 558.630, in paragraph (b)(2), remove ''Nos. 054771 and 069254'' and in its place add ''No. 054771''.

Dated: December 4, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31042 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2015–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) and two abbreviated new animal drug applications (ANADAs). This action is being taken at the sponsors' requests because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 21, 2015.

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: The following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
140–680 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN (tylosin phosphate) Premix	558.625
140–681 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix.	558.630
200–028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200–383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CLINDAROBE (clindamycin) Capsules	520.446

[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.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 *Notice of withdrawal of approval of application,* notice is given that approval of NADA 140–680, NADA 140–681, ANADA 200–028, and ANADA 200–383, and all supplements and amendments thereto, is hereby withdrawn, effective December 21, 2015.

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