significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR Part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E. O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9X, dated August 7, 2013, and effective September 15, 2013 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AAL AK E5 Kwigillingok, AK [Removed]

Issued in Seattle, Washington, on March 21, 2014.

Christopher Ramirez,

Acting Manager, Operations Support Group, Western Service Center.

[FR Doc. 2014–06800 Filed 3–31–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 526, and 558

[Docket No. FDA–2013–N–0002]

New Animal Drugs; Amprolium; Bambermycins; Ceftiofur; Deslorelin; Florfenicol; Florfenicol and Flunixin; Paclitaxel; Phenylbutazone; Pimobendan; Salinomycin; Tilmicosin; Tiludronate; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during January and February 2014. 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 previous approval of revised food safety warnings. This is being done to improve the accuracy of the regulations. The animal drug regulations are also being amended to reflect a change of sponsorship of an NADA and a change to a sponsor's address.

DATES: This rule is effective April 1, 2014.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during January and February 2014, 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.*

In addition, the regulations are being amended to reflect the previous approval of revised food safety warnings for florfenicol injectable solutions, florfenicol and flunixin combination drug injectable solution, ceftiofur hydrochloride intramammary infusions, and salinomycin medicated feeds. These amendments are being done to improve the accuracy of the regulations.

The regulations are also being amended to reflect two changes of sponsorship. Dechra, Ltd., Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–044 for OVUPLANT (deslorelin acetate implant) to Virbac AH, Inc., 3200 Meacham Blvd., Fort Worth, TX 76137. Also, West-Ward Pharmaceutical Corp., 465 Industrial Way West, Eatontown, NJ 07724, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–323 for Phenylbutazone Tablets to Hikma Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118. Accordingly, the Agency is amending the regulations to reflect these changes of sponsorship.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JANUARY AND FEBRUARY 2014

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–361	Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	PULMOTIL AC (tilmicosin phosphate) Concentrate Solution.	Original approval for the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.	520.2471	yes	EA/ FONSI [1].
141–420	Ceva Sante Animale, 10 Avenue de la Ballastière, 33500 Libourne, France.	TILDREN (tiludronate disodium).	Original approval for the control of clinical signs associated with navicular syndrome.	522.2473	yes	CE [2 3].
141–422	Oasmia Pharmaceutical AB, Vallongatan 1, SE–752 28, Uppsala, 75228 Sweden.	PACCAL VET–CA1 (paclitaxel for injection).	Conditional approval for the treatment of certain carcinomas in dogs that have not received previous chemotherapy or radiotherapy.	516.1684	yes	CE [2 3].
130–185	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	AMPROL 25% (amprolium) plus FLAVOMYCIN (bambermycins) Type A medicated articles.	Supplemental approval for prevention of coccidiosis caused by *Eimeria tenella* only or for prevention of coccidiosis where immunity to coccidiosis is not desired; and for increased rate of weight gain and improved feed efficiency in broiler chickens.	[4] 558.55	yes	CE [2 5].
141–246	Intervet, Inc., (d/b/a Merck Animal Health), 556 Morris Ave., Summit, NJ 07901.	AQUAFLOR (florfenicol) Type A medicated article.	Supplemental approval for an increase in the maximum daily dose for freshwater-reared finfish other than freshwater-reared warmwater finfish.	558.261	yes	EA/ FONSI [1].
141–273	Boehringer Ingelheim, Vetmedica, Inc., 2621 North Belt Hwy., St. Joseph, MO 64506–2002.	VETMEDIN (pimobendan) Chewable Tablets.	Supplemental approval for the addition of a 10-milligram chewable tablet.	520.1780	no	CE [2 6].

[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).
[2] 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 individually or cumulatively have a significant effect on the human environment.
[3] CE granted under 21 CFR 25.33(d)(1).
[4] The regulation in 21 CFR 558.55 has been amended in a separate rule (79 FR 10980, February 27, 2014).
[5] CE granted under 21 CFR 25.33(a)(2).
[6] CE granted under 21 CFR 25.33(a)(1).

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 Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 526

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 516, 520, 522, 526, 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.

■ 2. In § 510.600, in the table in paragraph (c)(1), alphabetically add entries for ''Hikma Pharmaceuticals LLC'' and ''Oasmia Pharmaceutical AB'', and remove the entry for ''West-Ward Pharmaceutical Corp.''; and in the table in paragraph (c)(2), numerically add entries for ''052818'' and ''059115'', and remove the entry for ''000143'' to 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
* * * * * * *	
Hikma Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118	059115
* * * * * * *	
Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden	052818
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
052818	Oasmia Pharmaceutical AB, Vallongatan 1, 75228 Uppsala, Sweden.
* * * * * * *	
059115	Hikma Pharmaceuticals LLC, P.O. Box 182400, Bayader Wadi Seer, Amman, Jordan 11118.
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for 21 CFR part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc, 360ccc–2, 371.

■ 4. Add § 516.1684 to subpart E to read as follows:

§ 516.1684 Paclitaxel.

(a) *Specifications.* Each vial of powder contains 60 milligrams (mg) paclitaxel. Each milliliter of constituted solution contains 1 mg paclitaxel.

(b) *Sponsor.* See No. 052818 in 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer 150 mg per square meter of body surface area intravenously over 15 to 30 minutes, once every 3 weeks, for up to 4 doses.

(2) *Indications for use.* For the treatment of nonresectable stage III, IV, or V mammary carcinoma in dogs that have not received previous chemotherapy or radiotherapy. For the treatment of resectable and nonresectable squamous cell carcinoma in dogs that have not received previous chemotherapy or radiotherapy.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. It is a violation of Federal law to use this product other than as directed in the labeling.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1780 [Amended].

■ 6. In paragraph (a) of § 520.1780, remove ''or 5 milligrams'' and in its place add ''5, or 10 milligrams''.

■ 7. Add § 520.2471 to read as follows:

§ 520.2471 Tilmicosin.

(a) *Specifications.* Each milliliter of concentrate solution contains 250 milligrams (mg) tilmicosin as tilmicosin phosphate.

(b) *Sponsor.* See No. 000986 in § 510.600(c) of this chapter.

(c) *Tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use in swine*—(1) *Amount.* Administer in drinking water at a concentration of 200 mg per liter for 5 consecutive days.

(2) *Indication for use.* For the control of swine respiratory disease associated with *Pasteurella multocida* and *Haemophilus parasuis* in groups of swine in buildings where a respiratory disease outbreak is diagnosed.

(3) *Limitations.* Swine intended for human consumption must not be slaughtered within 7 days of the last treatment with this product. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.533 [Amended]

■ 9. In paragraph (b)(1) of § 522.533, remove ''043246'' and in its place add ''051311''.

■ 10. In § 522.955, revise paragraphs (d)(1)(i)(C) and (d)(1)(ii)(C) to read as follows:

§ 522.955 Florfenicol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(C) *Limitations.* Do not slaughter within 44 days of treatment. This drug product 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 in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(ii) * * *

(C) *Limitations.* Do not slaughter within 28 days of last intramuscular treatment or within 38 days of subcutaneous treatment. This drug product 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 in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

■ 11. In § 522.956, revise paragraph (d)(3) to read as follows:

§ 522.956 Florfenicol and flunixin.

* * * * *

(d) * * *

(3) *Limitations.* Animals intended for human consumption must not be slaughtered within 38 days of treatment. This drug product 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 in preruminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 12. Add § 522.2473 to read as follows:

§ 522.2473 Tiludronate.

(a) *Specifications.* Each vial of powder contains 500 milligrams (mg) tiludronate disodium. Each milliliter of constituted solution contains 20 mg tiludronate disodium.

(b) *Sponsor.* See No. 013744 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer a single dose of 1 mg per kilogram (0.45 mg/pound) of body weight by intravenous infusion.

(2) *Indication for use.* For the control of clinical signs associated with navicular syndrome.

(3) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 13. The authority citation for 21 CFR part 526 continues to read as follows:

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

■ 14. In § 526.313, remove paragraph (d); redesignate paragraph (e) as paragraph (d); and revise newly redesignated paragraphs (d)(1)(iii) and (d)(2)(iii) to read as follows:

§ 526.313 Ceftiofur.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Milk taken from cows during treatment (a maximum of eight daily infusions) and for 72 hours after the last treatment must not be used for human consumption. Following label use for up to 8 consecutive days, a 2-day preslaughter withdrawal period is required. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in lactating dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

(2) * * *

(iii) *Limitations.* Milk taken from cows completing a 30-day dry-off period may be used for food with no milk discard due to ceftiofur residues. Following intramammary infusion, a 16-day preslaughter withdrawal period is required for treated cows. Following label use, no preslaughter withdrawal period is required for neonatal calves from treated cows regardless of colostrum consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits extra-label use of this drug in dry dairy cattle for disease prevention purposes; at unapproved doses; frequencies, durations, or routes of administration; and in unapproved major food producing species/production classes.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: 21 U.S.C. 360b, 371.

§ 558.261 [Amended]

■ 16. In § 558.261, in paragraph (e)(2)(ii), in the ''Limitations'' column, remove ''10 mg florfenicol'' and in its place add ''10 to 15 mg florfenicol''; and in paragraph (e)(2)(iii), in the ''Limitations'' column, remove ''10 mg florfenicol per kg of fish for''.

§ 558.550 [Amended]

■ 17. In § 558.550, in paragraph (d)(1)(i)(*c*), remove ''layers'' and in its place add ''laying hens producing eggs for human consumption''; and add at the end of paragraph (d)(2)(i)(*c*), ''Do not feed to laying hens producing eggs for human consumption.''

Dated: March 27, 2014.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2014–07220 Filed 3–31–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9644]

RIN 1545–BK44

Net Investment Income Tax; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations (TD 9644) that were published in the **Federal Register** on Monday, December 2, 2013 (78 FR 72394). The final regulations provide guidance on the general application of the Net Investment Income Tax and the computation of Net Investment Income.

DATES: This correction is effective April 1, 2014 and applicable December 2, 2013.

FOR FURTHER INFORMATION CONTACT: Adrienne M. Mikolashek, at (202) 317–6852 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations (TD 9644) that are the subject of this correction is under section 1411 of the Internal Revenue Code.

Need for Correction

As published, the final regulations (TD 9644) contain errors that may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Correction of Publication

Accordingly, 26 CFR part 1 is corrected by making the following correcting amendments:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 ***

■ **Par. 2.** Section 1.469–11 is amended by revising the first sentence of paragraph (b)(3)(iv)(C)(*1*) and the last sentence of paragraph (b)(3)(iv)(C)(*3*) *Example 4.* to read as follows:

§ 1.469–11 Effective date and transition rules.

* * * * *

(b) * * *

(3) * * *

(iv) * * *

(C) * * * (1) * * * An individual, estate, or trust also may regroup activities, in the manner described in paragraph (b)(3)(iv)(A) of this section, on an amended return only if the changes reported on such amended return cause the taxpayer to meet the Eligibility Criteria for the first time beginning in the taxable year for which the amended return is applicable and that the taxable year is not closed by the