individually or cumulatively have a significant effect on the human environment such that neither an environmental assessment nor an environmental impact statement is required. We have not received any new information or comments that would affect that determination.

**VII. Paperwork Reduction Act of 1995**

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

**VIII. Objections**

If you will be adversely affected by one or more provisions of this regulation, you may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections. You must separately number each objection, and within each numbered objection you must specify with particularity the provision(s) to which you object, and the grounds for your objection. Within each numbered objection, you must specifically state whether you are requesting a hearing on the particular provision that you specify in that numbered objection. If you do not request a hearing for any particular objection, you waive the right to a hearing on that objection. If you request a hearing, your objection must include a detailed description and analysis of the specific factual information you intend to present in support of the objection in the event that a hearing is held. If you do not include such a description and analysis for any particular objection, you waive the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

**IX. Section 301(*ll*) of the Federal Food, Drug, and Cosmetic Act**

Our review of this petition was limited to section 409 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348). This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(*ll*) of the FD&C Act (21 U.S.C. 331(*ll*)). Section 301(*ll*) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(*ll*)(1) to (4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(*ll*) of the FD&C Act or any of its exemptions apply to food containing this additive. Accordingly, this final rule should not be construed to be a statement that a food containing this additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(*ll*) of the FD&C Act. Furthermore, this language is included in all food additive final rules and therefore should not be construed to be a statement of the likelihood that section 301(*ll*) of the FD&C Act applies.

**X. References**

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*.

1. FDA Memorandum from H. Lee, to E. Anderson, June 18, 2014.
2. FDA Memorandum from A. Khan to E. Anderson, August 6, 2014.

**List of Subjects in 21 CFR Part 172**

Food additives, Incorporation by reference, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

## PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

■ 2. Amend § 172.185 as follows:

■ a. Revise paragraph (a);

■ b. Redesignate paragraphs (b) and (c) as paragraphs (c) and (d), respectively; and

■ c. Add new paragraph (b).

The revision and addition read as follows:

**§ 172.185 TBHQ.**

* * * * *

(a) The food additive has a melting point of not less than 126.5 °C.

(b) The percentage of TBHQ in the food additive is not less than 99.0 percent when tested by the assay described in the Food Chemicals Codex, 9th ed. (2014), pp. 1192–1194, which is incorporated by reference, or an equivalent method. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the United States Pharmacopeial Convention, 12601 Twinbrook Pkwy., Rockville, MD 20852 (Internet address: *http://www.usp.org*). Copies may be examined at the Food and Drug Administration's Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030 or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html*.

* * * * *

Dated: June 9, 2015.

**Susan Bernard,**

*Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.*

[FR Doc. 2015–14704 Filed 6–15–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

### 21 CFR Parts 510, 520, 522, 526, and 528

**[Docket No. FDA–2015–N–0002]**

### New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor

**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 March and April 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 several nonsubstantive changes. These technical amendments are being made to improve the accuracy of the regulations.

**DATES:** This rule is effective June 16, 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:** FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during March and April 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 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 MARCH AND APRIL 2015

| NADA/ ANADA | Sponsor | New animal drug product name | Action | 21 CFR sections | FOIA summary | NEPA review |
|---|---|---|---|---|---|---|
| 200–557 ..... | Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101. | Tiletamine-Zolazepam Injectable Solution (tiletamine HCl and zolazepam HCl). | Original approval as a generic copy of NADA 106–111. | 522.2470 | yes .. | CE[1] [2]. |
| 200–578 ..... | Belcher Pharmaceuticals, LLC, 6911 Bryan Dairy Rd., Largo, FL 33777. | Carprofen Flavored Tablets (carprofen). | Original approval as a generic copy of NADA 141–053. | 520.304 | yes .. | CE[1] [2]. |
| 200–579 ..... | Ceva Santé Animale, 10 Avenue de la Ballastière, 33500 Libourne, France. | Altrenogest Solution (altrenogest) | Original approval as a generic copy of NADA 141–222. | 520.48 | yes .. | CE[1] [2]. |
| 141–238 ..... | Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007. | SPECTRAMAST LC (ceftiofur intramammary suspension) Sterile Suspension. | Supplemental approval for treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *Streptococcus dysgalactiae* in lactating dairy cattle. | 526.313 | yes .. | CE[1] [3]. |
| 200–134 ..... | Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940. | FERTAGYL (gonadorelin) Sterile Solution. | Supplemental approval under section 512(b)(1) of the FD&C Act for use with cloprostenol injection to synchronize estrous cycles to allow for fixed time artificial insemination (FTAI) in lactating dairy cows. | 522.1077 | yes .. | EA/FONSI[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(a)(1).
[3] CE granted under 21 CFR 25.33(d)(5).
[4] 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).

In addition during March and April 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

| NADA/ ANADA | Previous sponsor | New animal drug product name | New sponsor | 21 CFR section |
|---|---|---|---|---|
| 140–883 ..... | Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201. | LEGEND (hyaluronate sodium) Injectable Solution. | Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096. | 522.1145 |
| 141–188 ..... | Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee, Mission, KS 66201. | MARQUIS (ponazuril) Antiprotozoal Oral Paste. | Merial, Inc., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096. | 520.1855 |
| 141–294 ..... | rEVO Biologics, 175 Crossing Blvd., Framingham, MA 01702. | Bc6 rDNA construct in GTC 155–92 goats. | LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702. | 528.1070 |

At this time, the regulations are being amended to reflect these changes of sponsorship.

Following these changes of sponsorship, LFB USA, Inc., is now the sponsor of an approved application.

Accordingly, § 510.600 (21 CFR 510.600) is being amended to add this

firm to the list of sponsors of approved applications.

The animal drug regulations are also being amended to reflect several non-substantive changes. These technical amendments are being made 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, 526, and 528*

Animal drugs.

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, 526, and 528 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), remove the entry for ''Abbott Laboratories'' and add in alphabetical order an entry for ''LFB USA, Inc.''; and in the table in paragraph (c)(2), remove the entry for 000044 and add in numerical order an entry for ''086047'' 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 |
|---|---|
| * * * * * | |
| LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702 | 086047 |
| * * * * * | |

(2) * * *

| Drug labeler code | Firm name and address |
|---|---|
| * * * * * | |
| 086047 | LFB USA, Inc., 175 Crossing Blvd., Framingham, MA 01702 |
| * * * * * | |

## 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.

■ 4. In § 520.48, revise paragraph (b) to read as follows:

**§ 520.48 Altrenogest.**

* * * * *

(b) *Sponsors.* See Nos. 000061 and 013744 in § 510.600(c) of this chapter.

* * * * *

**§ 520.88g [Amended]**

■ 5. In § 520.88g, in paragraph (c)(2)(i), remove ''(1 milliliter)''.

■ 6. In § 520.154a:

■ a. Revise the section heading;

■ b. In paragraphs (d)(1)(ii), (d)(2)(i)(A), (d)(2)(ii)(A), and (d)(4)(ii), remove ''bacitracin methylene disalicylate'' and in its place add ''bacitracin methylenedisalicylate''; and

■ c. In paragraph (d)(3)(ii), remove ''*Treponema hyodysenteriae''* and in its place add ''*Brachyspira hyodysenteriae''*.

The revision reads as follows:

**§ 520.154a Bacitracin methylenedisalicylate.**

* * * * *

**§ 520.304 [Amended]**

■ 7. In § 520.304, in paragraph (b)(3), remove ''No. 026637'' and in its place add ''Nos. 026637 and 062250''.

**§ 520.804 [Amended]**

■ 8. In § 520.804, redesignate paragraphs (c)(i), (c)(ii), and (c)(iii), as paragraphs (c)(1), (c)(2), and (c)(3).

■ 9. In § 520.1660d, revise paragraph (a)(4) to read as follows:

**§ 520.1660d Oxytetracycline powder.**

(a) * * *

(4) Each 2.73 grams of powder contains 1 gram of OTC HCl (packets: 2.46 and 9.87 oz, 3.09 and 3.91 lb; pail: 3.09 lb).

* * * * *

**§ 520.1855 [Amended]**

■ 10. In § 520.1855, in paragraph (b), remove ''000859'' and in its place add ''050604''.

■ 11. In § 520.2218, revise paragraphs (d)(1)(i)(A) and (B), and paragraphs (d)(2)(i)(A) and (B) to read as follows:

**§ 520.2218 Sulfamerazine, sulfamethazine, and sulfaquinoxaline powder.**

* * * * *

(d) * * *

(1) * * *

(i) * * *

(A) As an aid in the control of coccidiosis caused by *Eimeria tenella* and *E. necatrix* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. If bloody droppings appear, repeat at 0.025 percent level for 2 more days. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

* * * * *

(2) * * *

(i) * * *

(A) As an aid in the control of coccidiosis caused by *Eimeria meleagrimitis* and *E. adenoeides* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days, then plain water for 3 days, then medicated water (0.025 percent solution) for 2 days. Repeat if necessary. Do not change litter.

(B) As an aid in the control of acute fowl cholera caused by *Pasteurella multocida* susceptible to sulfamerazine, sulfamethazine, and sulfaquinoxaline: Provide medicated water (0.04 percent solution) for 2 to 3 days. If disease recurs, repeat treatment.

* * * * *

**§ 520.2640 [Amended]**

■ 12. In § 520.2640, in paragraphs (e)(2)(iii) and (e)(3)(iii), remove the first sentence.

## PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

**§§ 522.1073 and 522.1075 [Removed]**

■ 14. Remove §§ 522.1073 and 522.1075.

■ 15. Revise § 522.1077 to read as follows:

**§ 522.1077 Gonadorelin.**

(a) *Specifications.* Each milliliter (mL) of solution contains:

(1) 43 micrograms (µg) of gonadorelin as gonadorelin acetate;

(2) 100 µg of gonadorelin as gonadorelin acetate;

(3) 50 µg of gonadorelin as gonadorelin diacetate tetrahydrate; or

(4) 50 µg of gonadorelin as gonadorelin hydrochloride.

(b) *Sponsors.* See sponsor numbers in § 510.600(c) of this chapter.

(1) No. 000061 for use of the 43-µg/mL product described in paragraph (a)(1) as in paragraphs (d)(1)(i), (d)(1)(iv), and (d)(2) of this section.

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(ii), (d)(1)(v), and (d)(2) of this section.

(3) Nos. 000859 and 050604 for use of the 50-µg/mL product described in paragraph (a)(3) as in paragraphs (d)(1)(ii) and (d)(2) of this section.

(4) No. 054771 for use of the 50-µg/mL product described in paragraph (a)(4) as in paragraphs (d)(1)(iii), (d)(1)(vi), and (d)(2) of this section.

(c) *Special considerations.* Concurrent luteolytic drug use is approved as follows:

(1) Cloprostenol injection for use as in paragraph (d)(1)(iv) of this section as provided by No. 000061 in § 510.600(c) of this chapter.

(2) Cloprostenol injection for use as in paragraph (d)(1)(v) of this section as provided by No. 000061 or No. 068504 in § 510.600(c) of this chapter.

(3) Dinoprost injection for use as in paragraph (d)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

(d) *Conditions of use in cattle*—(1) *Indications for use and amounts*—(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin by intramuscular or intravenous injection.

(ii) For the treatment of ovarian follicular cysts in dairy cattle: Administer 100 µg gonadorelin by intramuscular or intravenous injection.

(iii) For the treatment of ovarian follicular cysts in cattle: Administer 100 µg gonadorelin by intramuscular injection.

(iv) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 86 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 86 µg gonadorelin by intramuscular injection.

(v) For use with cloprostenol injection to synchronize estrous cycles to allow for fixed-time artificial insemination (FTAI) in lactating dairy cows and beef cows: Administer to each cow 100 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 500 µg cloprostenol by intramuscular injection, followed 30 to 72 hours later by 100 µg gonadorelin by intramuscular injection.

(vi) For use with dinoprost injection to synchronize estrous cycles to allow fixed-time artificial insemination (FTAI) in lactating dairy cows: Administer to each cow 100 to 200 µg gonadorelin by intramuscular injection, followed 6 to 8 days later by 25 mg dinoprost by intramuscular injection, followed 30 to 72 hours later by 100 to 200 µg gonadorelin by intramuscular injection.

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

**§ 522.1145 [Amended]**

■ 16. In § 520.1145, in paragraph (e)(2)(i), remove ''000859'' and in its place add ''050604''.

■ 17. In § 522.2470, revise paragraph (b) to read as follows:

**§ 522.2470 Tiletamine and zolazepam for injection.**

* * * * *

(b) *Sponsors.* See Nos. 026637 and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 18. In § 522.2483, revise paragraph (b) to read as follows:

**§ 522.2483 Triamcinolone.**

* * * * *

(b) *Sponsors.* See Nos. 000010 and 054628 in § 510.600(c) of this chapter.

* * * * *

## PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 20. In § 526.313, revise paragraph (d)(1)(ii) to read as follows:

**§ 526.313 Ceftiofur.**

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For use in lactating dairy cattle:

(A) For the treatment of clinical mastitis associated with coagulase-negative staphylococci, *Streptococcus dysgalactiae,* and *Escherichia coli;* and

(B) For the treatment of diagnosed subclinical mastitis associated with coagulase-negative staphylococci and *S. dysgalactiae.*

* * * * *

## PART 528—NEW ANIMAL DRUGS IN GENETICALLY ENGINEERED ANIMALS

■ 21. The authority citation for 21 CFR part 528 continues to read as follows:

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

**§ 528.1070 [Amended]**

■ 22. In § 528.1070, in paragraph (b), remove ''042976'' and in its place add ''086047''.

Dated: June 11, 2015.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2015–14734 Filed 6–15–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF THE TREASURY

## Internal Revenue Service

## 26 CFR Parts 20, 25, and 602

**[TD 9725]**

**RIN 1545–BK74**

## Portability of a Deceased Spousal Unused Exclusion Amount

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations and removal of temporary regulations.

**SUMMARY:** This document contains final regulations that provide guidance under sections 2010 and 2505 of the Internal Revenue Code on the estate and gift tax applicable exclusion amount, in general, as well as on the applicable requirements for electing portability of a deceased spousal unused exclusion (DSUE) amount to the surviving spouse and on the applicable rules for the surviving spouse's use of this DSUE amount. The statutory provisions underlying the portability rules were enacted as part of the Tax Relief, Unemployment Insurance Reauthorization, and Job Creation Act of 2010, and these provisions were made permanent by the American Taxpayer Relief Act of 2012. The portability rules affect the estates of married decedents dying on or after January 1, 2011, and the surviving spouses of those decedents.

**DATES:**

*Effective Date.* These regulations are effective on June 12, 2015.

*Applicability Dates:* For specific dates of applicability of the final regulations,