This document is scheduled to be published in the Federal Register on 07/31/2014 and available online at **http://federalregister.gov/a/2014-17912**, and on **FDsys.gov**

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 529, and 558

[Docket No. FDA-2014-N-0002]

New Animal Drugs; Bacitracin Methylene Disalicylate; Dinoprost Solution; Gonadorelin Hydrochloride; Progesterone Intravaginal Inserts; Salinomycin; Ractopamine; Tylosin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 June 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 remove a cross-reference to a combination drug medicated feed that is no longer codified.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 June 2014 as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review 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 (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.

Also, the regulations are being amended in 21 CFR 558.76 to remove a cross-reference to a combination drug medicated feed which was removed in earlier corrections to part 558 (79 FR 10976, February 27, 2014). This amendment is 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.

Table 1--Original and Supplemental NADAs and ANADAs Approved During June 2014

NADA/ ANADA	Sponsor	New Animal Drug Product Name	Action	21 CFR Sections	FOIA Summary	NEPA Review
108-901	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	LUTALYSE (dinoprost injection) Injection	Supplemental approval of label references to approved uses with gonadorelin hydrochloride injection and progesterone intravaginal inserts	522.690, 522.1077, 529.1940	yes	CE[1,2]
128-686	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	BIO-COX 60 (salinomycin sodium) Type A medicated article	Supplemental approval of revised assay limits for Type A medicated articles	558.4	no	CE[1,2]
200-473[3]	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria	TYLOVET (tylosin tartrate) Soluble	Supplemental approval of a change in marketing status from over-the-counter (OTC) to by veterinary prescription (Rx)	520.2640	no	CE[1,2]
200-560	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	ACTOGAIN (ractopamine HCl), RUMENSIN (monensin), MGA (melengestrol acetate), and Type B and C medicated feeds	Original approval as a generic copy of NADA 141-234	558.500	yes	CE[1,2]
200-562	Zoetis Inc. 333 Portage St. Kalamazoo, MI 49007	ACTOGAIN (ractopamine HCl), RUMENSIN (monensin), TYLAN (tylosin phosphate), and MGA (melengestrol acetate) Type B and C medicated feeds	Original approval as a generic copy of NADA 141-233	558.500	yes	CE[1,2]

[1]The Agency has determined under 21 CFR 25.33 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.

[2]CE granted under 21 CFR 25.33(a)(1).

[3]The application listed was 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.

List of Subjects

21 CFR Parts 520, 522, and 529

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 520, 522, 529, and 558 are amended as follows:

PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.2640 [Amended]

2. In § 520.2640, in paragraphs (b)(1) and (d) remove "No. 000986" and in its place add "Nos. 000986 and 016592"; and in paragraph (b)(2) remove "Nos. 016592 and 061623" and in its place add "No. 061623".

PART 522--IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

4. In § 522.690, revise the section heading and paragraph (d)(2)(v) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(d) * * *

(2) * * *

(v) Dinoprost injection as provided by No. 054771 in § 510.600(c) of this chapter may also be used concurrently with gonadorelin hydrochloride injection as in § 522.1077 and with progesterone intravaginal inserts as in § 529.1940 of this chapter.

* * * * *

5. In § 522.1077, revise paragraph (c)(1)(ii) to read as follows:

§ 522.1077 Gonadorelin hydrochloride.

* * * * *

(c) * * *

(1) * * *

(ii) 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 mcg 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 mcg gonadorelin by intramuscular injection. Dinoprost injection as in § 522.690, provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 529--CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for 21 CFR part 529 continues to read as follows:

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

7. In § 529.1940, revise paragraph (d), the second sentence in paragraph (e)(1)(i) and the last sentence in paragraph (e)(1)(iii) to read as follows:

§ 529.1940 Progesterone intravaginal inserts.

* * * * *

(d) Special considerations. Product labeling shall bear the following warning: "Avoid contact with skin by wearing protective gloves when handling inserts. Store removed inserts in a sealable container until they can be disposed of in accordance with applicable local, state, and Federal regulations."

(e) * * *

(1) * * *

(i) * * * When used for indications listed in paragraph (e)(1)(ii)(A) of this section, administer 25 mg dinoprost as a single intramuscular injection 1 day prior to insert removal (Day 6). * * *

* * * * *

(iii) * * * Dinoprost injection for use in paragraphs (e)(1)(ii)(A) and (e)(1)(ii)(B) of this section as in § 522.690 of this chapter, provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

PART 558--NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.4 [Amended]

9. In paragraph (d) of § 558.4, in the "Category I" table, in the "Assay limits percent type A" column, in the entry for "Salinomycin", remove "95-115" and in its place add "90-110".

§ 558.76 [Amended]

10. In § 558.76, remove and reserve paragraph (d)(3)(vii).

§ 558.500 [Amended]

11. In § 558.500, in the table in paragraphs (e)(2)(viii) and (e)(2)(x), in the "Sponsor" column, remove "000986" and in its place add "000986, 054771".

Dated: July 24, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

[FR Doc. 2014-17912 Filed 07/30/2014 at 8:45 am; Publication Date: 07/31/2014]