

“dehumidifier,” that delivers cooled, conditioned air to an enclosed space, and is powered by single-phase electric current. It includes a source of refrigeration and may include additional means for air circulation and heating.

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## FEDERAL HOUSING FINANCE AGENCY

### 12 CFR Part 1238

[No. 2016-N-05]

#### Orders: Reporting by Regulated Entities of Stress Testing Results as of December 31, 2015; Summary Instructions and Guidance

**AGENCY:** Federal Housing Finance Agency.

**ACTION:** Orders.

**SUMMARY:** In this document, the Federal Housing Finance Agency (FHFA) provides notice that it issued Orders, dated March 2, 2016, with respect to stress test reporting as of December 31, 2015, under section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Summary Instructions and Guidance accompanied the Orders to provide testing scenarios.

**DATES:** Effective April 18, 2016. Each Order is applicable March 2, 2016.

**FOR FURTHER INFORMATION CONTACT:** Naa Awaa Tagoe, Senior Associate Director, Office of Financial Analysis, Modeling and Simulations, (202) 649-3140, [naawaa.tagoe@fhfa.gov](mailto:naawaa.tagoe@fhfa.gov); Stefan Szilagyi, Examination Manager, FHLBank Modeling, FHLBank Risk Modeling Branch (202) 649-3515, [stefan.szilagyi@fhfa.gov](mailto:stefan.szilagyi@fhfa.gov); Karen Heidel, Senior Counsel, Office of General Counsel, (202) 649-3073, [karen.heidel@fhfa.gov](mailto:karen.heidel@fhfa.gov); or Mark D. Laponsky, Deputy General Counsel, Office of General Counsel, (202) 649-3054, [mark.laponsky@fhfa.gov](mailto:mark.laponsky@fhfa.gov). The telephone number for the Telecommunications Device for the Hearing Impaired is (800) 877-8339.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FHFA is responsible for ensuring that the regulated entities operate in a safe and sound manner, including the maintenance of adequate capital and internal controls, that their operations and activities foster liquid, efficient, competitive, and resilient national housing finance markets, and that they

carry out their public policy missions through authorized activities. See 12 U.S.C. 4513. These Orders are being issued under 12 U.S.C. 4516(a), which authorizes the Director of FHFA to require by Order that the regulated entities submit regular or special reports to FHFA and establishes remedies and procedures for failing to make reports required by Order. The Orders, through the accompanying Summary Instructions and Guidance, prescribe for the regulated entities the scenarios to be used for stress testing. The Summary Instructions and Guidance also provides to the regulated entities advice concerning the content and format of reports required by the Orders and the rule.

##### II. Orders, Summary Instructions and Guidance

For the convenience of the affected parties and the public, the text of the Orders follows below in its entirety. You may access these Orders and the Summary Instructions and Guidance from FHFA's Web site at <http://www.fhfa.gov/SupervisionRegulation/DoddFrankActStressTests>. The Orders and Summary Instructions and Guidance also will be available for public inspection and copying at the Federal Housing Finance Agency, Eighth Floor, 400 Seventh St. SW., Washington, DC 20219. To make an appointment call (202) 649-3804.

The text of the Orders is as follows:

##### Federal Housing Finance Agency

*Order Nos. 2016-OR-B-1, 2016-OR-FNMA-1, and 2016-OR-FHLMC-1*

#### REPORTING BY REGULATED ENTITIES OF STRESS TESTING RESULTS AS OF DECEMBER 31, 2015

*Whereas*, section 165(i)(2) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”) requires certain financial companies with total consolidated assets of more than \$10 billion, and which are regulated by a primary Federal financial regulatory agency, to conduct annual stress tests to determine whether the companies have the capital necessary to absorb losses as a result of adverse economic conditions;

*Whereas*, FHFA's rule implementing section 165(i)(2) of the Dodd-Frank Act is codified as 12 CFR 1238 and requires that “[e]ach regulated entity must file a report in the manner and form established by FHFA.” 12 CFR 1238.5(b);

*Whereas*, The Board of Governors of the Federal Reserve System issued stress testing scenarios on January 28, 2016

and supplemented on February 4, 2016; and

*Whereas*, section 1314 of the Safety and Soundness Act, 12 U.S.C. 4514(a) authorizes the Director of FHFA to require regulated entities, by general or specific order, to submit such reports on their management, activities, and operation as the Director considers appropriate.

*Now Therefore*, it is hereby Ordered as follows:

Each regulated entity shall report to FHFA and to the Board of Governors of the Federal Reserve System the results of the stress testing as required by 12 CFR 1238, in the form and with the content described therein and in the Summary Instructions and Guidance, with Appendices 1 through 12 thereto, accompanying this Order and dated March 2, 2016.

*It Is So Ordered*, this the 2nd day of March, 2016.

This Order is effective immediately.

Signed at Washington, DC, this 2nd day of March, 2016.

Melvin L. Watt,  
Director, Federal Housing Finance Agency.

Dated: April 12, 2016.

Melvin L. Watt,  
Director, Federal Housing Finance Agency.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 520, 522, 524, 529, 556, and 558

[Docket No. FDA-2016-N-0002]

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

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA, 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 January and February 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 applications that occurred in January and February.  
**DATES:** This rule is effective April 18, 2016.

**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](mailto: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 January and February 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 JANUARY AND FEBRUARY 2016

File No.	Sponsor	Product name	Action	21 CFR section	FOIA summary	NEPA review
141-444 ...	Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW United Kingdom.	ZYCORTAL Suspension (desoxycorticosterone pivalate injectable suspension).	Original approval for use as replacement therapy for mineralocorticoid deficiency in dogs with primary hypoadrenocorticism (Addison's disease).	522.535	yes .....	CE. <sup>1,2</sup>
141-448 ...	Lloyd, Inc., 604 W. Thomas Ave., Shenandoah, IA 51601.	THYRO-TABS CANINE (levothyroxine sodium tablets).	Original approval for replacement therapy for diminished thyroid function in dogs.	520.1248	yes .....	CE. <sup>1,2</sup>
141-452 ...	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPARICA (sarolaner) Chewables.	Original approval for killing adult fleas, and for the treatment and prevention of flea infestations and the treatment and control of tick infestations in dogs.	520.2086	yes .....	CE. <sup>1,2</sup>
141-263 ...	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	CERENIA (maropitant citrate) Injectable Solution.	Supplemental approval providing for intravenous administration in dogs and cats.	522.1315	yes .....	CE. <sup>1,2</sup>
141-449 ...	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE-GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate.	Supplemental approval for the treatment and control of certain nematode worms in swine, except for nursing piglets; and of a revised tolerance in swine liver.	520.905a, 556.275	yes .....	EA/FONSI. <sup>3</sup>
200-600 ...	ECO LLC, 344 Nassau St., Princeton, NJ 08540.	WORMX (pyrantel pamoate) Flavored Tablets.	Original approval as a generic copy of NADA 139-191.	520.2041	yes .....	CE. <sup>1,2</sup>

<sup>1</sup> 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.

<sup>2</sup> CE granted under 21 CFR 25.33(d)(1).

<sup>3</sup> 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).

Also, FDA is amending the regulations to reflect the approval of several minor supplemental applications that revised classes of food-producing animals in indications and in food safety warnings for decoquinat and robenidine in medicated feeds. A

food safety precautionary statement has also been revised for use of monensin in medicated chicken feed.

**II. Changes of Sponsorship**

Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee,

Mission, KS 66201 has informed FDA that it has transferred ownership of, and all rights and interest in, the following approved applications to Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product name	21 CFR section
006-391 ...	S.Q. (sulfaquinoxaline) 40% Medicated Feed .....	558.586
006-677 ...	S.Q. (sulfaquinoxaline) 20% Solution .....	520.2325a
007-087 ...	Sulfaquinoxaline Solubilized .....	520.2325a

File No.	Product name	21 CFR section
033–157 ...	SPECTAM Scour Halt (spectinomycin dihydrochloride pentahydrate) Solution .....	520.2123c
040–040 ...	SPECTAM (spectinomycin) Injectable Solution .....	522.2120
048–287 ...	Oxytetracycline-50 (oxytetracycline hydrochloride) Injection .....	522.1662a
065–110 ...	PEN-G-MAX (penicillin G procaine) Injectable Suspension .....	522.1696b
065–498 ...	DUAL-CILLIN (benzathine penicillin G and procaine penicillin G) Injectable Suspension .....	522.1696a
119–142 ...	PVL Iron Dextran (iron hydrogenated dextran) Injectable .....	522.1182
128–089 ...	ZONOMETH (dexamethasone) Injectable Solution .....	522.540
140–270 ...	SULFASURE SR (sulfamethazine) Sustained-Release Cattle Bolus .....	520.2260b
200–068 ...	Oxytetracycline Hydrochloride 100 mg/mL Injection .....	522.1662a
200–108 ...	Dexamethasone Injectable Solution .....	522.540
200–118 ...	Neomycin (neomycin sulfate) Oral Solution .....	520.1484
200–123 ...	MAXIM-200 (oxytetracycline) Injection .....	522.1660a
200–147 ...	GENTA-JECT (gentamicin sulfate) Injectable Solution .....	522.1044
200–153 ...	NEO 200 (neomycin sulfate) Oral Solution .....	520.1484
200–162 ...	Tripelennamine Hydrochloride Injection .....	522.2615
200–174 ...	Gentamicin Sulfate Pig Pump Oral Solution .....	520.1044b
200–177 ...	Sulfadimethoxine Injection 40% .....	522.2220
200–192 ...	Sulfadimethoxine 12.5% Oral Solution .....	520.2220a
200–219 ...	Ivermectin Pour-On for Cattle .....	524.1193
200–463 ...	Amprolium-P 9.6% Oral Solution .....	520.100

Also, Strategic Veterinary Pharmaceuticals, Inc., 100 NW. Airport Rd., St. Joseph, MO 64503 has informed

FDA that it has transferred ownership of, and all rights and interest in, the following applications to Phibro Animal

Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., Suite 21, Teaneck, NJ 07666.

File No.	Product name	21 CFR section
038–200 ...	OXY WS (oxytetracycline) Soluble Antibiotic .....	520.1660d
065–178 ...	FERMYCIN (chlortetracycline) Soluble .....	520.441
065–496 ...	Tetracycline Soluble Powder .....	520.2345d

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 approved applications to

Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria:

File No.	Product name	21 CFR section
006–891 ...	SUL-Q-NO <sub>x</sub> (sulfaquinoxaline) Soluble Powder .....	520.2325a
065–140 ...	TET-SOL 324 (tetracycline hydrochloride) Soluble Powder .....	520.2345d
100–094 ...	POULTRY-SULFA (sulfamerazine, sulfamethazine, and sulfaquinoxaline) Soluble Powder .....	520.2218
128–686 ...	BIO-COX (salinomycin) Type A Medicated Article .....	558.550
130–435 ...	OXY-TET (oxytetracycline hydrochloride) Soluble Powder/Solution .....	520.1660d
134–284 ...	BIO-COX/FLAVOMYCIN (bambermycins) .....	558.550
200–106 ...	R-PEN (Penicillin G potassium) Soluble Powder .....	520.1696b
200–130 ...	NEO-SOL 50 (neomycin sulfate) Soluble Powder .....	520.1484
200–189 ...	Lincomycin Soluble Powder .....	520.1263c
200–441 ...	AUREOMYCIN (chlortetracycline) Soluble Powder .....	520.441

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship.

### III. Technical Amendments

FDA has noticed that it failed to amend all necessary regulations to reflect the change of sponsorship of an oxytetracycline soluble powder (80 FR 13226, March 13, 2015). At this time, we are amending 21 CFR 529.1660 to include the drug labeler code for the new sponsor. This action is being taken to improve the accuracy of the regulations.

FDA has also noticed that in § 558.355 (21 CFR 558.355) use of bacitracin

methylenedisalicylate at 100 to 200 grams/ton in combination with monensin in broiler and replacement chicken feeds was codified in error for NADA 141–140 (66 FR 13236, March 5, 2001). At this time, § 558.355 is amended by removing paragraphs (f)(1)(xxx) and (f)(4)(v). In addition, paragraph (f)(4)(iv), a remnant of a previous technical amendment (79 FR 10963, February 27, 2014), is also being removed. We have also noticed that certain paragraphs describing approved conditions of use were removed in error from § 558.355 during codification of a supplemental application to NADA 138–456 that increased the dose range for monensin used in combination with

bacitracin methylenedisalicylate in broiler chicken feed (57 FR 6554, February 26, 1992). At this time, § 558.355 is amended by adding paragraphs (f)(1)(xxiv)(a) and (b). These actions are being taken to improve the accuracy of the regulations.

FDA has noticed that in error we removed the approved conditions of use for gleptoferron, an injectable iron used to prevent anemia in young piglets. At this time, 21 CFR 522.1055 is being added. This action is being taken 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 Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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, 524, 529, 556, and 558 are amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

#### § 520.100 [Amended]

■ 2. In § 520.100, remove and reserve paragraph (b)(3).

■ 3. In § 520.441, revise paragraph (b)(1), remove paragraph (b)(2); redesignate paragraphs (b)(3) and (4) as paragraphs (b)(2) and (3); and revise newly redesignated paragraph (b)(2). The revisions read as follows:

#### § 520.441 Chlortetracycline powder.

\* \* \* \* \*

(b) \* \* \*

(1) Nos. 000010, 016592, 054771, and 069254 for use as in paragraph (d) of this section.

(2) No. 066104 for use as in paragraphs (d)(4)(i)(A), (d)(4)(i)(B), and (d)(4)(ii) through (d)(4)(iv) of this section.

\* \* \* \* \*

■ 4. In § 520.905a, in paragraph (a), remove “paragraph (e)(5)” and in its place add “paragraphs (e)(5) and (6)”; and add paragraph (e)(6) to read as follows:

#### § 520.905a Fenbendazole suspension.

\* \* \* \* \*

(e) \* \* \*

(6) *Swine, except for nursing piglets—*  
(i) *Amount.* Administer orally via the drinking water at a daily dose of 2.2 mg/kg of body weight (1.0 mg/lb) for 3 consecutive days.

(ii) *Indications for use.* For the treatment and control of lungworms: Adult *Metastrongylus apri*, adult *M. pudendotectus*; gastrointestinal worms: Adult and larvae (L3, L4 stages, liver, lung, intestinal forms) large

roundworms (*Ascaris suum*); nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyostromylus rubidus*): Adult and larvae (L2, L3, L4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and kidney worms: Adult and larvae *Stephanurus dentatus*.

(iii) *Limitations.* Swine intended for human consumption must not be slaughtered within 2 days from the last treatment.

#### § 520.1044b [Amended]

■ 5. In § 520.1044b, in paragraph (b), remove “000859” and in its place add “016592”.

■ 6. Add § 520.1248 to read as follows:

#### § 520.1248 Levothyroxine.

(a) *Specifications.* Each tablet contains 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, or 1.0 milligrams (mg) levothyroxine sodium.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use—*(1) *Amount.* Administer by mouth 0.1 mg/10 pounds of body weight (0.022 mg/kilogram) as a single dose every 24 hours or as a divided dose every 12 hours.

(2) *Indications for use.* For replacement therapy for diminished thyroid function in dogs.

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

■ 7. In § 520.1263c, revise paragraph (b) to read as follows:

#### § 520.1263c Lincomycin powder.

\* \* \* \* \*

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

(1) No. 016592 for use as in paragraph (d) of this section.

(2) Nos. 054925, 061623, and 076475 for use as in paragraphs (d)(1) and (d)(2) of this section.

\* \* \* \* \*

#### § 520.1484 [Amended]

■ 8. In § 520.1484, in paragraph (b)(2), remove “054771” and in its place add “016592, 054771,”; and in paragraph (b)(3), remove “000859” and in its place add “016592”.

#### § 520.1660d [Amended]

■ 9. In § 520.1660d, in paragraph (b)(2), remove “054771” and in its place add “016592”; and in paragraph (b)(3), remove “054628” and in its place add “066104”.

#### § 520.1696b [Amended]

■ 10. In § 520.1696b, in paragraph (b), in numerical order add “016592”.

#### § 520.1705 [Amended]

■ 11. In § 520.1705, in paragraph (a), remove “pergolide mesylate” and in its place add “pergolide (as pergolide mesylate)”.

#### § 520.2041 [Amended]

■ 12. In § 520.2041, in paragraph (b), remove “Nos. 017135 and 051311” and in its place add “Nos. 017135, 051311, and 066916”.

■ 13. Add § 520.2086 to read as follows:

#### § 520.2086 Sarolaner.

(a) *Specifications.* Each chewable tablet contains 5, 10, 20, 40, 80, or 120 milligrams (mg) sarolaner.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—*(1) *Amount.* Administer orally once a month at the recommended minimum dosage of 0.9 mg/lb (2 mg/kg).

(2) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Amblyomma maculatum* (Gulf Coast tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs 6 months of age or older and weighing 2.8 pounds or more.

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

#### § 520.2123c [Amended]

■ 14. In § 520.2123c, in paragraph (b), remove “000859” and in its place add “016592”.

#### § 520.2218 [Amended]

■ 15. In § 520.2218, in paragraph (b), remove “054771” and in its place add “016592”.

#### § 520.2220a [Amended]

■ 16. In § 520.2220a, in paragraph (b)(1), remove “000859” and in its place add “016592”.

#### § 520.2260b [Amended]

■ 17. In § 520.2260b, in paragraph (f)(1), remove “000859” and in its place add “016592”.

#### § 520.2325a [Amended]

■ 18. In § 520.2325a, in paragraph (a)(1), remove “000859” and in its place add “016592”; and in paragraph (a)(3), remove “No. 054771” and in its place add “Nos. 016592 and 054771”.

■ 19. In § 520.2345d, in paragraph (b)(2), remove “054628” and in its place add “066104”; in paragraph (b)(3),

remove “No. 054771” and in its place add “Nos. 016592 and 054771”; and revise the first sentence in paragraph (d)(1)(iii) and paragraph (d)(2)(iii) to read as follows:

**§ 520.2345d Tetracycline powder.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 4 days of treatment for No. 066104 and within 5 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.\* \* \*

(2) \* \* \*

(iii) *Limitations.* Administer for 3 to 5 days; do not slaughter animals for food within 7 days of treatment for No. 066104 and within 4 days of treatment for Nos. 016592, 054771, 054925, 057561, 059130, and 061623; prepare a fresh solution daily; use as the sole source of tetracycline.

\* \* \* \* \*

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

■ 20. The authority citation for part 522 continues to read as follows:

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

■ 21. Revise § 522.535 to read as follows:

**§ 522.535 Desoxycorticosterone.**

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams (mg) of desoxycorticosterone pivalate.

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

(1) No. 043264 for use as in paragraphs (c)(1)(i), (c)(2)(i), and (c)(3) of this section.

(2) No. 058198 for use as in paragraphs (c)(1)(ii), (c)(2)(ii), and (c)(3) of this section.

(c) *Conditions of use—(1) Amount.* (i) Administer an initial dose of 2.2 mg/kilogram (1 mg/lb) of body weight by subcutaneous injection. Subsequent dosages should be individualized according to label instructions based on patient response to therapy.

(ii) Dosage requirements are variable and must be individualized on the basis of the response of the patient to therapy. Initial dose of 1 milligram per pound (0.45 kilogram) of body weight every 25 days, intramuscularly. Usual dose is 0.75 to 1.0 milligram per pound of body weight every 21 to 30 days.

(2) *Indications for use—(i)* For use as replacement therapy for mineralocorticoid deficiency in dogs

with primary hypoadrenocorticism (Addison's Disease).

(ii) For use as replacement therapy for the mineralocorticoid deficit in dogs with primary adrenocortical insufficiency.

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

**§ 522.540 [Amended]**

■ 22. In § 522.540, in paragraphs (a)(2)(i) and (d)(2)(i), remove “000859” and in its place add “016592”.

**§ 522.1044 [Amended]**

■ 23. In § 522.1044, in paragraph (b)(4), remove “000859” and in its place add “016592”.

■ 24. Add § 522.1055 to read as follows:

**§ 522.1055 Gleptoferron.**

(a) *Specifications.* Each milliliter contains the equivalent of 200 milligrams (mg) of elemental iron as gleptoferron (complex of ferric hydroxide and dextran glucoheptonic acid).

(b) *Sponsor.* See No. 059120 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used in young piglets as follows:

(1) *Amounts and indications for use—*

(i) Administer 200 mg of elemental iron intramuscularly on or before 3 days of age for prevention of iron deficiency anemia.

(ii) Administer 200 mg of elemental iron intramuscularly for treatment of iron deficiency anemia.

(2) [Reserved]

**§ 522.1182 [Amended]**

■ 25. In § 522.1182, in paragraph (b)(6), remove “000859” and in its place add “016592”; and remove paragraph (b)(8).

**§ 522.1315 [Amended]**

■ 26. In § 522.1315, in paragraphs (c)(1)(i) and (c)(2)(i), remove “subcutaneous injection” and in its place add “subcutaneous or intravenous injection”.

**§ 522.1660a [Amended]**

■ 27. In § 522.1660a, in paragraph (b), remove “000859” and in its place add “016592”.

**§ 522.1662a [Amended]**

■ 28. In § 522.1662a, in paragraphs (h)(2) and (i)(2), remove “000859” and in its place add “016592”.

**§ 522.1696a [Amended]**

■ 29. In § 522.1696a, in paragraph (b)(2), remove “000859” and in its place add “016592”.

**§ 522.1696b [Amended]**

■ 30. In § 522.1696b, in paragraph (b)(1), remove “000859” and in its place add “016592”.

**§ 522.2120 [Amended]**

■ 31. In § 522.2120, in paragraph (b), remove “000859” and in its place add “016592”.

**§ 522.2220 [Amended]**

■ 32. In § 522.2220, in paragraph (b)(3), remove “000859” and in its place add “016592”.

**§ 522.2615 [Amended]**

■ 33. In § 522.2615, in paragraph (b), remove “000859” and in its place add “016592”.

**PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 34. The authority citation for part 524 continues to read as follows:

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

**§ 524.1193 [Amended]**

■ 35. In paragraph (b)(2) of § 524.1193, remove “000859” and in its place add “016592”.

**§ 524.1484k [Amended]**

■ 36. In § 522.1484k, revise the section heading to read: *Neomycin and prednisolone suspension.*

**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

■ 37. The authority citation for part 529 continues to read as follows:

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

**§ 529.1660 [Amended]**

■ 38. In § 529.1660, in paragraph (b)(2), remove “048164, 054771, and 061623” and in its place add “054771, 061623, and 069254”.

**PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

■ 39. The authority citation for part 556 continues to read as follows:

*Authority:* 21 U.S.C. 342, 360b, 371.

■ 40. In § 556.275, in paragraph (b)(2)(i), remove “6 ppm” and in its place add “3.2 ppm”; redesignate paragraphs (b)(3) and (4) as paragraphs (b)(4) and (5); and add new paragraph (b)(3) and paragraph (c) to read as follows:

**§ 556.275 Fenbendazole.**

\* \* \* \* \*

(b) \* \* \*

(3) *Chickens*—(i) *Liver (the target tissue)*. The tolerance for fenbendazole sulfone (the marker residue) is 5.2 ppm.  
(ii) [Reserved]

\* \* \* \* \*

(c) *Related conditions of use*. See §§ 520.905a, 520.905c, 520.905d, 520.905e, and 558.258 of this chapter.

## PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

### § 558.195 [Amended]

■ 42. Amend § 558.195 as follows:

■ a. In the table in paragraph (e)(1)(i), in the “Limitations” column, remove “Do not feed to laying chickens.” and in its place add “Do not feed to laying hens producing eggs for human consumption.”;

■ b. In the table in paragraph (e)(2)(i), in the “Limitations” column, remove “Do not feed to cows producing milk for food.” and in its place add “Do not feed to cows producing milk for human consumption.”;

■ c. In the table in paragraphs (e)(3)(i)1. and (e)(3)(ii)1., in the “Limitations” column, remove “Do not feed to sheep producing milk for food.” and in its place add “Do not feed to sheep producing milk for human consumption.”; and

■ d. In the table in paragraphs (e)(3)(i)2. and (e)(3)(ii)2., in the “Limitations” column, remove “Do not feed to goats producing milk for food.” and in its place add “Do not feed to goats producing milk for human consumption.”

■ 43. In § 558.340, redesignate paragraphs (c)(1)(i) and (ii) as paragraphs (c)(2) and (3); and revise newly redesignated paragraph (c)(2) to read as follows:

### § 558.340 Maduramicin.

\* \* \* \* \*

(c) \* \* \*

(2) *Indications for use*. Broiler chickens: For prevention of coccidiosis caused by *Eimeria acervulina*, *E. tenella*, *E. brunetti*, *E. maxima*, *E. necatrix*, and *E. mivati*.

\* \* \* \* \*

■ 44. In § 558.355, revise paragraph (f)(1)(xxiv); and revise paragraph (f)(1)(xxv) introductory text and remove and reserve paragraphs (f)(1)(xxx), (f)(4)(iv), and (f)(4)(v).

The revisions read as follows:

### § 558.355 Monensin.

\* \* \* \* \*

(f) \* \* \*

(1) \* \* \*

(xxiv) *Amount per ton*. Monensin, 90 to 110 grams, plus bacitracin methylenedisalicylate, 4 to 50 grams.

(a) *Indications for use*. For improved feed efficiency; as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*.

(b) *Limitations*. Do not feed to laying chickens; feed continuously as sole ration; in the absence of coccidiosis, the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain; as bacitracin methylenedisalicylate provided by No. 054771 in § 510.600(c) of this chapter.

(xxv) *Amount per ton*. Monensin, 90 to 110 grams, plus bacitracin zinc, 4 to 50 grams.

\* \* \* \* \*

### § 558.515 [Amended]

■ 45. In § 558.515, in the table in paragraph (d), in the entry for “30 (0.0033 pct)”, in the first entry under the “Indications for use” column, remove “For broiler and fryer chickens:” and in its place add “Broiler chickens:”; and in the first entry under the “Limitations” column, remove “Do not feed to layers.” and in its place add “Do not feed to chickens producing eggs for food.”

### § 558.550 [Amended]

■ 46. Amend § 558.550 as follows:

■ a. In paragraph (b)(1), remove “054771” and in its place add “016592”;

■ b. Remove paragraph (b)(2) and redesignate paragraph (b)(3) as paragraph (b)(2);

■ c. In paragraph (d)(1)(xvi)(c), remove “Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by Nos. 054771 and 016592 in § 510.600(c) of this chapter.” and in its place add “Chlortetracycline as provided by Nos. 054771 and 069254; salinomycin as provided by No. 016592 in § 510.600(c) of this chapter.”;

■ d. In paragraph (d)(1)(xx)(C) and (xxi)(C), remove “Salinomycin as provided by 054771; bacitracin methylene disalicylate as provided by 054771 in § 510.600(c) in this chapter.” and in its place add “Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) in this chapter.”;

■ e. In paragraph (d)(1)(xxii)(B), remove “Salinomycin as provided by Nos. 016592 and 054771; tylosin phosphate as provided by Nos. 000986 and 016592

in § 510.600(c) of this chapter.” and in its place add “Salinomycin as provided by No. 016592; tylosin phosphate as provided by Nos. 000986 and 016592 in § 510.600(c) of this chapter.”;

■ f. In paragraph (d)(1)(xxiii)(b), remove “Salinomycin as provided by Nos. 054771 and 016592; bambermycins by No. 016592 in § 510.600(c) of this chapter.” and in its place add “Salinomycin and bambermycins as provided by No. 016592 in § 510.600(c) of this chapter.”;

■ g. In paragraphs (d)(3)(ii)(B), (iii)(B), and (v)(B), remove “Salinomycin as provided by 054771; bacitracin methylene disalicylate as provided by 054771 in § 510.600(c) of this chapter.” and in its place add “Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in § 510.600(c) of this chapter.”; and

■ h. In paragraph (d)(4)(i)(b), remove “Salinomycin as provided by Nos. 054771 and 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.” and in its place add “Salinomycin as provided by No. 016592; oxytetracycline as provided by No. 066104 in § 510.600(c) of this chapter.”

### § 558.586 [Amended]

■ 47. In § 558.586, in paragraph (b), remove “000859” and in its place add “016592”.

Dated: April 12, 2016.

**Tracey Forfa,**

*Acting Director, Center for Veterinary Medicine.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 870

[Docket No. FDA–2011–N–0650]

### Cardiovascular Devices; Reclassification of External Pacemaker Pulse Generator Devices; Reclassification of Pacing System Analyzers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a final order to reclassify external pacemaker pulse generator (EPPG) devices, which are currently preamendments class III devices (regulated under product code