DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2011–N–0003]

New Animal Drugs; Change of Sponsor; Zinc Gluconate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for zinc gluconate injectable solution from Technology Transfer, Inc., to Ark Sciences, Inc.

DATES: This rule is effective December 21, 2011.

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, (240) 276–8300, email: *steven.vaughn@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Technology Transfer, Inc., 33 East Broadway, suite 190, Columbia, MO 65203 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141–217 for NEUTERSOL (zinc gluconate) Injectable Solution to Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218. Accordingly, the Agency is amending the regulations in 21 CFR 522.2690 to reflect the transfer of ownership.

Following this change of sponsorship, Technology Transfer, Inc., is no longer the sponsor of an approved application. Accordingly, § 510.600 (21 CFR 510.600) is being amended to remove the entries for this firm.

In addition, Ark Sciences, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, § 510.600 is being amended to add entries for this sponsor.

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 522

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 and 522 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 ''Technology Transfer, Inc.''; alphabetically add a new entry for ''Ark Sciences, Inc.''; and in the table in paragraph (c)(2), remove the entry for ''067647''; and in numerical sequence add a new entry for ''076175'' 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
* * * * *	
Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218	076175
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
076175	Ark Sciences, Inc., 1101 East 33rd St., suite B304, Baltimore, MD 21218.
* * * * *	

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.

§ 522.2690 [Amended]

■ 4. In paragraph (b) of § 522.2690, remove ''067647'' and in its place add ''076175''.

Dated: December 8, 2011.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2011–32591 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2011–N–0003]

New Animal Drugs for Use in Animal Feeds; Monensin

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 of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, A Division of Eli Lilly & Co. The supplemental NADA revises a manufacturing specification for monensin free-choice Type C medicated feed for growing cattle on pasture or in dry lot.

DATES: This rule is effective December 21, 2011.

FOR FURTHER INFORMATION CONTACT: Matthew A. Lucia, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, (240) 276–8116, email: *matthew.lucia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for use of RUMENSIN 90 (monensin, USP) Type A medicated article in a free-choice Type C medicated feed for growing cattle on pasture or in dry lot (stocker and feeder cattle and dairy and beef replacement heifers). The supplement revises the percent monensin Type A medicated article in the codified free-choice feed specifications to reflect use of a product containing 90.7 grams of monensin per pound. The supplemental NADA is approved as of May 24, 2011, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The Agency has determined under 21 CFR 25.33 that this action is of a type

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

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 in 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 part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 2. In § 558.355, revise paragraph (f)(3)(x) introductory text and paragraph (f)(3)(x)(*b*) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(x) *Amount per ton.* 1,620 grams monensin, USP.

* * * * *

(*b*) *Specifications.* Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–082
Sodium chloride (salt)	24.37	6–04–152
Dried cane molasses	20.0	4–04–695
Ground limestone (33% calcium) or calcium carbonate (38% calcium)	13.75	6–02–632
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix [1]	2.5	
Monensin Type A article, 90.7 grams per pound	0.89	
Antidusting oil	1.0	

[1] Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

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Dated: December 9, 2011.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 2011–32427 Filed 12–20–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF LABOR

Equal Employment Opportunity Commission

29 CFR Part 1602

Recordkeeping and Reporting Requirements Under Title VII, the ADA and GINA

CFR Correction

In Title 29 of the Code of Federal Regulations, Parts 900 to 1899, revised as of July 1, 2011, in Part 1602, remove the words ''section 709(c) of title VII or section 107 of the ADA'' and add in their place the words ''section 709(c) of title VII, section 107 of the ADA, or section 207(a) of GINA'' wherever they appear in the following sections:

Section	Page No.
§ 1602.11	175
§ 1602.12	175
§ 1602.19	177
§ 1602.26	179
§ 1602.37	181
§ 1602.45	184
§ 1602.54	186

[FR Doc. 2011–32746 Filed 12–20–11; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2011–1099]

Drawbridge Operation Regulations; Annisquam River and Blynman Canal, Gloucester, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the SR127 Bridge at mile 0.0 across the Annisquam River and Blynman Canal. The deviation is necessary to facilitate bridge rehabilitation repairs. This deviation allows the bridge to remain in the closed position for 31 days.

DATES: This deviation is effective from December 19, 2011 through January 18, 2012.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2011–1099 and are available online at *www.regulations.gov,* inserting USCG–2011–1099 in the ''Keyword'' and then clicking ''Search''. They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. John McDonald, Project Officer, First Coast Guard District, *john.w.mcdonald@uscg.mil,* or telephone (617) 223–8364. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366–9826.

SUPPLEMENTARY INFORMATION: The SR127 Bridge, across the Annisquam River/Blynman Canal, mile 0.0, at Gloucester, Massachusetts, has a vertical clearance in the closed position of 7 feet at mean high water and 16 feet at mean low water. The drawbridge operation regulations are listed at 33 CFR 117.586.

The owner of the bridge, Massachusetts Department of Transportation, requested a temporary deviation from the regulations to