

7217, section 19(b)(2) of the Act, 15 U.S.C. 78s(b)(2), and section 19(b)(3) of the Act, 15 U.S.C. 78s(b)(3), to institute proceedings to determine whether a proposed rule change of the Public Company Accounting Oversight Board should be disapproved and to provide to the Public Company Accounting Oversight Board notice of the grounds for disapproval under consideration. In addition, pursuant to section 107 of the Sarbanes-Oxley Act of 2002, 15 U.S.C. 7217, and section 19(b)(2)(B) of the Act, 15 U.S.C. 78s(b)(2)(B), to extend for a period not exceeding 240 days from the date of publication of notice of the filing of a proposed rule change pursuant to section 19(b)(1) of the Act, 15 U.S.C. 78s(b)(1), the period during which the Commission must issue an order approving or disapproving the proposed rule change and to determine whether such longer period is appropriate and publish the reasons for such determination.

(5) Pursuant to section 107 of the Sarbanes-Oxley Act of 2002, 15 U.S.C. 7217, and section 19(b)(3)(C) of the Act, 15 U.S.C. 78s(b)(3)(C), to temporarily suspend a rule of the Public Company Accounting Oversight Board.

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Dated: January 11, 2011.

By the Commission.

Elizabeth M. Murphy,
Secretary.

[FR Doc. 2011-835 Filed 1-14-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

[Docket No. FDA-2010-N-0002]

New Animal Drugs; 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 a change of sponsor for hemoglobin glutamer-200 from Biopure Corp. to OPK Biotech, LLC.

DATES: This rule is effective January 18, 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, e-mail: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Biopure Corp., 11 Hurley St., Cambridge, MA 02141 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-067 for OXYGLOBIN (hemoglobin glutamer-200) to OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA 02141. There is no change in drug labeler code.

Following this change of sponsorship, Biopure Corp. is no longer the sponsor of an approved application. In addition, OPK Biotech, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, § 510.600 is being amended to reflect these changes.

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 510

Administrative practice and procedure, Animal drugs, Labeling, 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 Center for Veterinary Medicine, 21 CFR part 510 is 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 “Biopure Corp.”; and alphabetically add a new entry for “OPK Biotech, LLC”; and in the table in paragraph (c)(2), revise the entry for “063075” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

Firm name and address	Drug labeler code
* * * * *	
(c) * * *	
(1) * * *	
* * * * *	
OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA 02141	063075
* * * * *	
(2) * * *	

Drug labeler code	Firm name and address
* * * * *	
063075	OPK Biotech, LLC, 11 and 39 Hurley St., Cambridge, MA 02141
* * * * *	

Dated: January 11, 2011.
Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 2011-904 Filed 1-14-11; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA-2010-N-0002]

New Animal Drugs; Change of Sponsor; Follicle Stimulating Hormone

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 follicle stimulating hormone from AUSA International, Inc., to Therio, Inc.

DATES: This rule is effective January 18, 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, e-mail: steven.vaughn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: AUSA International, Inc., Rt. 8, P.O. Box 324-12, Tyler, TX 75703 has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-014 for SUPER-OV (follicle stimulating hormone) to Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503. Accordingly, the Agency is amending the regulations in 21 CFR 522.1002 to reflect the transfer of ownership.

Following this change of sponsorship, AUSA International, 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, Therio, 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 "Ausa International, Inc.;" and alphabetically add a new entry for "Therio, Inc.;" and in the table in paragraph (c)(2), remove the entry for "059521;" and in numerical sequence add a new entry for "052923" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *
(c) * * *
(1) * * *

Table with 2 columns: Firm name and address, Drug labeler code. Row 1: Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503, 052923

(2) * * *

Table with 2 columns: Drug labeler code, Firm name and address. Row 1: 052923, Therio, Inc., 8801 Anderson Ave., Manhattan, KS 66503

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.

§ 522.1002 [Amended]

■ 4. In paragraph (a)(2) of § 522.1002, remove "059521" and add in its place "No. 052923".

Dated: January 12, 2011.

Steven D. Vaughn,

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

[FR Doc. 2011-909 Filed 1-14-11; 8:45 am]

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DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 24

[Docket Number: OSHA-2007-0028]

RIN 1218-AC25

Procedures for the Handling of Retaliation Complaints Under the Employee Protection Provisions of Six Environmental Statutes and Section 211 of the Energy Reorganization Act of 1974, as Amended

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Final rule.

SUMMARY: This document provides the final text of regulations governing the employee protection (or "whistleblower") provisions of Section 211 of the Energy Reorganization Act of 1974, as amended, ("ERA"), implementing the statutory changes enacted into law on August 8, 2005, as part of the Energy Policy Act of 2005. The regulations also finalize changes to the procedures for handling retaliation complaints under Section 211 of the ERA and the six environmental whistleblower statutes that were designed to make them as consistent as possible with the more recently promulgated procedures for handling

retaliation complaints under other whistleblower provisions administered by the Occupational Safety and Health Administration (OSHA).

DATES: This final rule is effective on January 18, 2011.

FOR FURTHER INFORMATION CONTACT: Nilgun Tolek, Director, Office of the Whistleblower Protection Program, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-3610, 200 Constitution Avenue, NW., Washington, DC 20210; telephone (202) 693-2199.

SUPPLEMENTARY INFORMATION:

I. Background

The Energy Policy Act of 2005, Public Law 109-58, was enacted on August 8, 2005. Among other provisions, this new law amended the employee protection provisions for nuclear whistleblowers under Section 211 of the ERA, 42 U.S.C. 5851; the statutory amendments affect only ERA whistleblower complaints. The changes to the regulations also affect the six environmental whistleblower statutes because the same procedures generally apply to each of the statutes covered in 29 CFR part 24. Because OSHA recognizes the importance of consistency in the procedures governing the whistleblower statutes that it administers, it has tried to standardize these regulations with other whistleblower regulations promulgated by OSHA to the extent possible within the bounds of the statutory language. We have removed from this background section as unnecessary and confusing the statement in the interim final rule that the 2005 ERA amendments apply to claims filed on or after August 8, 2005; OSHA takes no position in these regulations on the applicability of the 2005 ERA amendments to complaints filed with the Department before August 8, 2005.

II. Summary of Statutory Changes to ERA Whistleblower Provisions

Section 629 of Public Law 109-58 (119 Stat. 785) amended Section 211 of the ERA, 42 U.S.C. 5851, by making the changes described below.

Revised Definition of "Employer"

Section 211 of the ERA defined a covered "employer" to include: Licensees of the Nuclear Regulatory Commission ("Commission"); applicants for such licenses, and their contractors and subcontractors; contractors and subcontractors of the Department of Energy, except those involved in naval nuclear propulsion work under Executive Order 12344; licensees of an