

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.

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

Firm name and address	Drug labeler code
* * * *	*
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.

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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.