4160-01-P

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 [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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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.

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