



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

[Docket No. FDA-2012-N-0002]

New Animal Drugs; Change of Sponsor; Change of Sponsor Address; Lincomycin and Spectinomycin Soluble Powder; Sulfadimethoxine Oral Solution and Soluble Powder; Tiamulin

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 three abbreviated new animal drug applications (ANADAs) from Teva Animal Health, Inc., to Phibro Animal Health Corp. FDA is also amending the regulations to reflect a change of sponsor's address for Phibro Animal Health Corp. and for Eka Chemicals, Inc.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Teva Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-258 for Sulfadimethoxine Soluble Powder, ANADA 200-344 for Tiamulin Soluble Antibiotic, and ANADA 200-345 for Lincomycin-Spectinomycin Soluble Powder to Phibro Animal Health Corp., 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660.

In addition, Phibro Animal Health Corp. has informed FDA of a change of address to GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666. Eka Chemicals, Inc., 1775 West Oak Commons Ct., Marietta, GA 30062 has informed FDA of a change of address to 1850 Parkway Pl. SE., suite 1200, Marietta, GA 30067. Accordingly, the Agency is amending the regulations in 21 CFR 510.600 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

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

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 520 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), revise the entries for “Eka Chemicals, Inc.” and “Phibro Animal Health”; and in the table in paragraph (c)(2), revise the entries for “061088” and “066104” 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
* * * * *	
Eka Chemicals, Inc., 1850 Parkway Pl. SE., suite 1200, Marietta, GA 30067	061088
* * * * *	
Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666	066104
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
061088	Eka Chemicals, Inc., 1850 Parkway Pl. SE., suite 1200, Marietta, GA 30067
* * * * *	
066104	Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666
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PART 520--ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1265 [Amended]

4. In paragraph (b)(2) of § 520.1265, remove “Nos. 057561, 059130, and 061623” and in its place add “Nos. 057561, 061623, and 066104”.

§ 520.2220a [Amended]

5. In paragraph (a)(2) of § 520.2220a, remove “Nos. 000069, 054925, 057561, 058829, 059130, and 061623” and in its place add “Nos. 000069, 054925, 057561, 058829, 061623, and 066104”.

§ 520.2455 [Amended]

6. In paragraph (b)(2) of § 520.2455, remove “No. 059130” and in its place add “No. 066104”.

Dated: September 6, 2012.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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