4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

[Docket No. FDA-2011-N-0003]

New Animal Drugs; Change of Sponsor; Chlortetracycline Powder

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 an abbreviated new animal drug application (ANADA) for chlortetracycline soluble powder from Teva Animal Health, Inc., to Quo Vademus, LLC.

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

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: 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 200-236 for Chlortetracycline HCL Soluble Powder to Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349. Accordingly, the Agency is amending the regulations in 21 CFR 520.441 to reflect the transfer of ownership.

Quo Vademus, LLC, is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 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 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), alphabetically add a new entry for "Quo Vademus, LLC"; and in the table in paragraph (c)(2), in numerical sequence add a new entry for "076475" 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
* * * * *	
Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349	076475
* * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * *	
076475	Quo Vademus, LLC, 277 Faison McGowan Rd., Kenansville, NC 28349
* * * * *	

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.

§ 520.441 [Amended]

4. In paragraph (b)(4) of § 520.441, remove "059130" and in its place add "076475".

Dated: February 1, 2012.

William T. Flynn,

Acting Director,

Center for Veterinary Medicine.

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