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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 510 and 522**

Display Date 2-12-08  
Publication Date 2-13-08  
Certifier Skese

**New Animal Drugs; Change of Sponsor; Ketamine**

**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 ketamine hydrochloride injectable solution from Veterinary Research Associates, Inc., to Putney, Inc.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: *david.newkirk@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** Veterinary Research Associates, Inc., 2817 West Country Rd., 54G, Fort Collins, CO 80524, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-073 for Ketamine Hydrochloride Injection, USP, to Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101. Accordingly, the regulations are amended in 21 CFR 522.1222a to reflect this change of sponsorship.

Following these changes of sponsorship, Veterinary Research Associates, Inc., is no longer the sponsor of an approved application. In addition, Putney, Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to

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ANADA 200-073

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remove the entries for Veterinary Research Associates, Inc., and to add entries for Putney, Inc.

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 “Veterinary Research Associates, Inc.” and alphabetically add a new entry for “Putney, Inc.”; and in the table in paragraph (c)(2) remove the entry for “064408” and numerically add an entry for “026637” 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
.	.
Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101	026637
.	.

(2) \* \* \*

Drug labeler code	Firm name and address
.	.
026637	Putney, Inc., 400 Congress St., suite 200, Portland, ME 04101
.	.

**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.

**§ 522.1222a [Amended]**

■ 4. In § 522.1222a, revise paragraph (b) by removing “064408” and numerically adding “026637”.

Dated: Jan 31, 08  
January 31, 2008.

Dr. Bernadette Dunham  
Bernadette Dunham,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

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