DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA–2009–N–0665]

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 Bioniche Animal Health USA, Inc., to Bioniche Teoranta.

DATES: This rule is effective December 16, 2009.

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: Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200–257 for Ketamine HCl (ketamine hydrochloride injection, USP) to Bioniche Teoranta, Inverin, County Galway, Ireland. Accordingly, the agency is amending the regulations in 21 CFR 522.1222a to reflect the transfer of ownership.

In addition, Bioniche Teoranta 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 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) alphabetically add a new entry for ''Bioniche Teoranta''; and in the table in paragraph (c)(2) numerically add a new entry for ''063286'' 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
* * *	* *
Bioniche Teoranta, Inverin, County Galway, Ireland	063286
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
063286	Bioniche Teoranta, Inverin, County Galway, Ireland
* *	* * *

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 paragraph (b) of § 522.1222a, remove ''064847'' and add in its place ''063286''.

Dated: December 10, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–29888 Filed 12–15–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2009–N–0665]

Implantation or Injectable Dosage Form New Animal Drugs; Florfenicol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA adds *Mycoplasma bovis* to the bovine respiratory disease pathogens for which florfenicol injectable solution is approved as a treatment.

DATES: This rule is effective December 16, 2009.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 56 Livingston Ave., Roseland, NJ 07068, filed a supplement to NADA 141–265 that provides for use of NUFLOR GOLD (florfenicol) Injectable Solution for treatment of bovine respiratory disease in beef and non-lactating dairy cattle. The supplement adds *Mycoplasma bovis* to the list of pathogens for which use of this product is approved. The supplemental NADA is approved as of September 4, 2009, and the regulations are amended in 21 CFR 522.955 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under 21 CFR 25.33 that this action is of a type