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]

BILLING CODE 4160–01–S

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

that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 2. In § 522.955, revise paragraph (d)(1)(i)(B) and in paragraph (d)(1)(i)(C), in the first sentence, remove ''last'' to read as follows:

§ 522.955 Florfenicol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(B) *Indications for use.* For treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, *Histophilus somni*, and *Mycoplasma bovis* in beef and non-lactating dairy cattle.

* * * * *

Dated: December 10, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–29875 Filed 12–15–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 260

Outer Continental Shelf Oil and Gas Leasing

CFR Correction

In Title 30 of the Code of Federal Regulations, Parts 200 to 699, revised as of July 1, 2009, on page 549, in § 260.122, reinstate paragraphs (b)(2) and (b)(3) to read as follows:

§ 260.122 How long will a royalty suspension volume be effective for a lease issued in a sale held after November 2000?

* * * * *

(b) * * *

(2) You must pay any royalty due under this paragraph, plus late payment interest under § 218.54 of this title, no later than 90 days after the end of the period for which royalty is owed.

(3) Any production on which you must pay royalty under this paragraph will count toward the production volume determined under §§ 260.120 through 260.124.

* * * * *

[FR Doc. E9–30016 Filed 12–15–09; 8:45 am]

BILLING CODE 1505–01–D

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0802; FRL–8798–5]

2,6-Diisopropylnaphthalene (2,6-DIPN); Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of 2,6-diisopropylnaphthalene (2,6-DIPN), including its metabolites and degradates, resulting from post-harvest applications to potatoes, in or on various commodities. Loveland Products, Incorporated requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA). The tolerances will expire on May 18, 2012.

DATES: This regulation is effective December 16, 2009. Objections and requests for hearings must be received on or before February 16, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0802. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Leonard Cole, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5412; e-mail address: *cole.leonard@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Access Electronic Copies of this Document?

In addition to accessing electronically available documents at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.