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22. From the Commission's Home Page on the Internet, this information is available on eLibrary. The full text of this document, including the Appendix, is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

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the Public Reference Room at public.referenceroom@ferc.gov.

E. Effective Date and Congressional Notification

24. These regulations are effective March 27, 2012. The Commission has determined, with the concurrence of the Administrator of the Office of Information and Regulatory Affairs of OMB, that this rule is not a "major rule" as defined in section 351 of the Small Business Regulatory Enforcement Fairness Act of 1996. The rule is being submitted to the Senate, House, Government Accountability Office, and the Small Business Administration.

List of Subjects in 18 CFR Part 284

Continental shelf, Natural gas, Reporting and recordkeeping requirements.

By the Commission.
Nathaniel J. Davis, Sr.,
Deputy Secretary.

In consideration of the foregoing, the Commission amends Part 284, Chapter I,

Title 18, *Code of Federal Regulations*, as follows.

PART 284—CERTAIN SALES AND TRANSPORTATION OF NATURAL GAS UNDER THE NATURAL GAS POLICY ACT OF 1978 AND RELATED AUTHORITIES

■ 1. The authority citation for part 284 continues to read as follows:

Authority: 15 U.S.C. 717-717w, 3301-3432; 42 U.S.C. 7101-7352; 43 U.S.C. 1331-1356.

§ 284.13 [Amended]

■ 2. Section 284.13 is amended as follows:

■ a. Paragraph (e) is removed.

■ b. Paragraph (f) is redesignated as paragraph (e).

§ 284.126 [Amended]

■ 3. Section 284.126 is amended by removing paragraph (c).

Appendix

LIST OF COMMENTERS AND ABBREVIATIONS

Commenter	Abbreviation
American Gas Association	AGA.
Cranberry Pipeline Corporation	Cranberry.
Enogex LLC	Enogex.
Enstor Operating Company, LLC	Enstor.
Interstate Natural Gas Association of America	INGAA.
Jefferson Island Storage & Hub, LLC	Jefferson.
Niska Gas Storage LLC	Niska.
Northern Natural Gas Company	Northern.
Spectra Energy Transmission, LLC & Spectra Energy Partners, LP	Spectra.
Texas Pipeline Association	TPA.
Williston Basin Interstate Pipeline Company	Williston Basin.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

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

New Animal Drugs; Change of Sponsor's Name

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's name from

Nycomed US, Inc., to Fougera Pharmaceuticals, Inc.

DATES: This rule is effective January 27, 2012.

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: Nycomed US, Inc., 60 Baylis Rd., Melville, NY 11747 has informed FDA of a change of name to Fougera Pharmaceuticals, Inc. Accordingly, the Agency is amending the regulations in 21 CFR 510.600(c) 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 in 21 CFR Part 510

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

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 510 is 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 "Nycomed US, Inc."; alphabetically add a new entry for "Fougera Pharmaceuticals, Inc."; and in the table

in paragraph (c)(2), revise the entry for "025463".

The addition and revision 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	
* * * * *	* * *	* * *
Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747	025463	
* * * * *	* * *	* * *
(2) * * *		
Drug labeler code	Firm name and address	
* * * * *	* * *	* * *
025463	Fougera Pharmaceuticals, Inc., P.O. Box 2006, 60 Baylis Rd., Melville, NY 11747.	
* * * * *	* * *	* * *

Dated: January 24, 2012.
William T. Flynn,
Acting Director, Center for Veterinary Medicine.
 [FR Doc. 2012-1756 Filed 1-26-12; 8:45 am]
BILLING CODE 4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

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

Oral Dosage Form New Animal Drugs; Milbemycin Oxime, Lufenuron, and Praziquantel

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 new animal drug application (NADA) filed by Novartis Animal Health US, Inc. The NADA provides for the veterinary prescription use of milbemycin oxime, lufenuron, and praziquantel for the prevention of

heartworm disease, for prevention and control of fleas, and for the treatment and control of various internal parasites in dogs.

DATES: This rule is effective January 27, 2012.

FOR FURTHER INFORMATION CONTACT:

Steven Fleischer, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8234, email: steven.fleischer@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., Suite 300, Greensboro, NC 27408, filed NADA 141-333 that provides for the veterinary prescription use of SENTINEL SPECTRUM (milbemycin oxime/lufenuron/praziquantel) Tablets for the prevention of heartworm disease, for the prevention and control of flea populations, and for the treatment and control of adult roundworm, adult hookworm, adult whipworm, and adult tapeworm infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older. The NADA is approved as of December 8, 2011, and 21 CFR part 520 is amended by adding new § 520.1447 to reflect the approval.

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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this 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 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 2. Add § 520.1447 to read as follows:

§ 520.1447 Milbemycin oxime, lufenuron, and praziquantel tablets.

(a) *Specifications.* Each tablet contains:

(1) 2.3 milligrams (mg) milbemycin oxime, 46 mg lufenuron, and 22.8 mg praziquantel;

(2) 5.75 mg milbemycin oxime, 115 mg lufenuron, and 57 mg praziquantel;

(3) 11.5 mg milbemycin oxime, 230 mg lufenuron, and 114 mg praziquantel; or

(4) 23 mg milbemycin oxime, 460 mg lufenuron, and 228 mg praziquantel.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 0.5 mg milbemycin oxime, 10 mg lufenuron, and 5 mg of praziquantel per kilogram of body weight, once a month.

(ii) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis*; for the prevention and control of flea populations (*Ctenocephalides felis*); and for the treatment and control of adult roundworm (*Toxocara canis*, *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, and *E. granulosus*) infections in dogs and puppies 2 pounds of body weight or greater and 6 weeks of age and older.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

Dated: January 23, 2012.

William T. Flynn,
Acting Director, Center for Veterinary Medicine.

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