

to protect system reliability. The Transmission Provider and the wind plant Interconnection Customer shall determine what SCADA information is essential for the proposed wind plant, taking into account the size of the plant and its characteristics, location, and importance in maintaining generation resource adequacy and transmission system reliability in its area.

## Appendix C

[Note: These provisions to be adopted as APPENDIX 7 to the LGIP]

## Appendix 7 —Interconnection Procedures for a Wind Generating Plant

Appendix 7 sets forth procedures specific to a wind generating plant. All other requirements of this LGIP continue to apply to wind generating plant interconnections.

### A. Special Procedures Applicable to Wind Generators

The wind plant Interconnection Customer, in completing the Interconnection Request required by section 3.3 of this LGIP, may provide to the Transmission Provider a set of preliminary electrical design specifications depicting the wind plant as a single equivalent generator. Upon satisfying these and other applicable Interconnection Request conditions, the wind plant may enter the queue and receive the base case data as provided for in this LGIP.

No later than six months after submitting an Interconnection Request completed in this manner, the wind plant Interconnection Customer must submit completed detailed electrical design specifications and other data (including collector system layout data) needed to allow the Transmission Provider to complete the System Impact Study.

Joseph T. Kelliher, Chairman, *dissenting in part*:

I vote for this order because it constitutes an improvement over the final rule. I agree with the Commission's decision to grant rehearing with respect to the low voltage ride-through (LVRT) provisions and to adopt the joint recommendation of NERC and AWEA. As the order points out, by adopting a definitive, uniform, LVRT standard, the Commission "provide[s] certainty" to the industry and "ensure[s] that reliability is maintained and NERC planning standards are met."<sup>1</sup>

Unfortunately, the Commission's decision on LVRT contrasts with its decision to exempt wind generators from compliance with the same power factor standard as all other generators. The Commission requires all non-wind generators to maintain a power factor within the range of 0.95 leading to 0.95 lagging, which NERC has determined to be "within a range required by Good Utility Practice."<sup>2</sup> Order No. 661, however, singles out wind generators for special treatment by exempting them from meeting the standard power factor requirement unless the Transmission Provider demonstrates in the System Impact Study that reactive power capability is necessary to ensure the safety or

reliability of the transmission system. In my view, exempting only wind generators from the power factor standard does not provide certainty to the industry, results in an undue preference for wind generators and does not adequately ensure that reliability of the transmission system is maintained.

Section 205 of the Federal Power Act broadly precludes public utilities, in any transmission or sale subject to the Commission's jurisdiction, from "mak[ing] or grant[ing] any undue preference or advantage to any person or subject[ing] any person to any undue prejudice or disadvantage." \* \* \*<sup>3</sup> In my view, Order No. 661 gives preferential treatment to wind generators, since it exempts wind generators from meeting the same power factor requirement as all other non-wind generators. The issue is whether the preferential treatment afforded to wind generators is undue.

I do not believe that either the record or the explanation offered in this order provides a basis for giving preferential treatment to wind generators when it comes to meeting the power factor requirement. The order's attempt to justify discriminating in favor of wind generators as an accommodation for "technical differences"<sup>4</sup> is not convincing. The only "technical" difference identified is the assertion that compliance with reactive power capability is more expensive for wind generators than for other generator resources.<sup>5</sup> While one can understand why wind generators would like to be relieved of the added cost of complying with the same power factor standard as all other non-wind generators, I fail to see how the desire to avoid incurring the costs of complying with the Commission's standardized power factor requirement constitutes a technological difference warranting discriminatory treatment.

Equally troubling, I disagree with the Commission's decision to brush aside the concerns raised by NERC and other protesters that the Commission has "lowered the bar" for reliability by shifting the burden to the Transmission Provider to justify the need for wind generators to comply with the same power factor requirement as non-wind generators. I find little comfort in the Commission's view that any reliability concerns can be addressed in the System Impact Study if the Transmission Provider proves that a wind generator's compliance with the reactive power factor standard is necessary. In my view, shifting the burden to Transmission Providers to make such a showing simply cannot be reconciled with the approach taken by the Commission in Order No. 2003 which presumes the need for all generators to comply with power factor requirement under "Good Utility Practice."<sup>6</sup>

As a result, I would have granted rehearing and returned to the approach proposed by the Commission in the NOPR of requiring all

<sup>3</sup> 16 U.S.C. 824d(b).

<sup>4</sup> Order at P45.

<sup>5</sup> *Id.* ("One of these [technical] differences is that for wind plants, reactive power capability is a significant added cost, while it is not a significant additional cost for traditional generators.").

<sup>6</sup> Order No. 2003 at PP541-42.

generators to meet the same power factor standard absent a waiver by the Transmission Provider. Accordingly, I dissent in part from the order.

Joseph T. Kelliher.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Moxidectin Gel; Moxidectin and Praziquantel Gel

**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 two supplemental new animal drug applications (NADAs) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADAs provide for oral use of moxidectin gel or moxidectin and praziquantel gel in horses and ponies for the treatment and control of two additional species of small strongyles.

**DATES:** This rule is effective December 19, 2005.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543, e-mail: [mberson@cvm.fda.gov](mailto:mberson@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 141-087 for QUEST (moxidectin 2.0%) Gel and to NADA 141-216 for QUEST Plus (moxidectin 2.0%/praziquantel 12.5%) Gel. Both products are used for the treatment and control of various species of internal parasites in horses and ponies. The supplements provide for the addition of two new species of adult small strongyles to product labeling. The supplemental NADAs are approved as of November 23, 2005, and 21 CFR 520.1452 and 520.1453 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications

<sup>1</sup> Order at P34.

<sup>2</sup> Order No. 2003 at P541.

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)), these approvals qualify for 3 years of marketing exclusivity beginning November 23, 2005. Exclusivity applies only to the effectiveness claim for adult *Cylicocyclus radiatus* and *Petrovinema poculatus* for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) that these actions are of a type that do 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.

**§ 520.1452 [Amended]**

■ 2. Section 520.1452 is amended in paragraph (d)(2) as follows:

a. By removing "and *C. nassatus*;" and adding in its place "*C. nassatus*, and *C. radiatus*;" and

b. By removing "and *Gyalocephalus capitatus*;" and adding in its place "*Gyalocephalus capitatus*; and *Petrovinema poculatus*;".

**§ 520.1453 [Amended]**

■ 3. Section 520.1453 is amended in paragraph (d)(2) as follows:

a. By removing "and *C. nassatus*;" and adding in its place "*C. nassatus*, and *C. radiatus*;" and

b. By removing "and *Gyalocephalus capitatus*;" and adding in its place "*Gyalocephalus capitatus*; and *Petrovinema poculatus*;".

Dated: December 8, 2005.

**Bernadette A. Dunham,**

*Deputy Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 520 and 558**

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

**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 four approved new animal drug applications (NADAs) for oral dosage forms and feed uses of tiamulin from Boehringer Ingelheim Vetmedica, Inc., to Novartis Animal Health US, Inc.

**DATES:** This rule is effective December 19, 2005.

**FOR FURTHER INFORMATION CONTACT:** David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: *david.newkirk@fda.gov*.

**SUPPLEMENTARY INFORMATION:** Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506-2002, has informed FDA that it has transferred ownership of, and all rights and interest in, the following four approved NADAs, to Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408:

NADA Number	Trade Name
134-644	DENAGARD (tiamulin) Soluble Antibiotic
139-472	DENAGARD (tiamulin) 25% Premixes
140-916	DENAGARD (tiamulin) Liquid Concentrate
141-011	DENAGARD (tiamulin)/chlortetracycline

Accordingly, the agency is amending the regulations in 21 CFR 520.2455, 520.2456, and 558.600 to reflect the transfer of ownership and a current format.

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 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 520 and 558 are 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. Revise § 520.2455 to read as follows:

**§ 520.2455 Tiamulin.**

(a) *Specifications.* (1) Each ounce of concentrate solution contains 3.64 grams (12.3 percent) tiamulin hydrogen fumarate.

(2) Each gram of soluble powder contains 450 milligrams (mg) tiamulin hydrogen fumarate.

(b) *Sponsors.* See Nos. 058198 and 059130 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.738 of this chapter.

(d) *Special considerations.* (1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur.

(2) Do not use in swine weighing over 250 pounds (lb).

(e) *Conditions of use in swine—(1) Amounts and indications for use.* Administer in drinking water for 5 consecutive days:

(i) 3.5 mg per (l) lb of body weight daily for treatment of swine dysentery associated with *Brachyspira hyodysenteriae* susceptible to tiamulin.

(ii) 10.5 mg/lb of body weight daily for treatment of swine pneumonia due to *Actinobacillus pleuropneumoniae* susceptible to tiamulin.

(2) *Limitations.* Withdraw medication 3 days before slaughter following treatment at 3.5 mg/lb and 7 days before slaughter following treatment at 10.5 mg/lb of body weight. Prepare fresh medicated water daily. Use as only source of drinking water.