[FR Doc. 04–10237 Filed 5–4–04; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Liquid

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 an abbreviated new animal drug application (ANADA) filed by Veterinary Laboratories, Inc. The ANADA provides for oral use of ivermectin solution in horses for the treatment and control of various species of internal and cutaneous parasites.

DATES: This rule is effective May 5, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215, filed ANADA 200–341 that provides for oral use of SPARMECTIN–E (ivermectin) Liquid for Horses for the treatment and control of various species of internal and cutaneous parasites. Veterinary Laboratories' SPARMECTIN–E Liquid for Horses is approved as a generic copy of Merial Ltd.'s EQVALAN (ivermectin) Oral Liquid for Horses, approved under NADA 140–439. The ANADA is approved as of March 8, 2004, and the regulations are amended in 21 CFR 520.1195 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

The agency has determined under 21 CFR 25.33(a)(1) 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 Subject 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.

§ 520.1195 [Amended]

■ 2. Section 520.1195 is amended in paragraph (b)(1) by adding ''000857'' in numerical sequence.

Dated: April 23, 2004.

Catherine P. Beck,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 04–10193 Filed 5–4–04; 8:45 am]
BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin 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 a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for oral use of moxidectin gel in horses and ponies for the treatment and control of an additional species of small strongyle.

DATES: This rule is effective May 5, 2004.

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*.

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, used for the treatment and control of various species of internal parasites in horses and ponies. The supplemental NADA provides for the addition of one new species of adult small strongyle and for the speciation of adult small strongyles in product labeling. The supplemental NADA is approved as of March 17, 2004, and 21 CFR 520.1452 is amended 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 approval qualifies for 3 years of marketing exclusivity beginning March 17, 2004. Exclusivity applies only to the new effectiveness claim for adult *Coronocyclus labratus* for which new data were required.

The agency has determined under 21 CFR 25.33(d)(1) 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. Section 520.1452 is amended by revising the heading of paragraph (d) and by revising paragraph (d)(2) to read as follows:

§ 520.1452 Moxidectin gel.

* * * * *

(d) *Conditions of use in horses and ponies*—* * *

(2) *Indications for use.* For the treatment and control of large strongyles: *Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), and *T. serratus* (adults); small strongyles (adults): *Cyathostomum* spp., including *C. catinatum* and *C. pateratum*; *Cylicocyclus.* spp., including *C. insigne*, *C. leptostomum*, and *C. nassatus*; *Cyliocostephanus. spp.*, including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*; *Coronocyclus* spp., including *C. coronatus*, *C. labiatus*, and *C. labratus*; and *Gyalocephalus capitatus*; small strongyles: undifferentiated lumenal larvae; encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids: *Parascaris equorum* (adults and L4 larval stages); pinworms: *Oxyuris equi* (adults and L4 larval stages); hairworms: *Trichostrongylus axei* (adults); large-mouth stomach worms: *Habronema muscae* (adults); and horse stomach bots: *Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars). One dose also suppresses strongyle egg production for 84 days.

* * * * *

Dated: April 14, 2004.

Steven D. Vaughn,

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

[FR Doc. 04–10210 Filed 5–4–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 206

RIN 1010–AD04

Federal Oil Valuation

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: MMS is amending the existing regulations governing the valuation of crude oil produced from Federal leases for royalty purposes, and related provisions governing the reporting thereof. The current regulations became effective on June 1, 2000.

These amendments primarily affect which published market prices are most appropriate to value crude oil not sold at arm's length and what transportation deductions should be allowed.

DATES: *Effective date:* July 6, 2004.

FOR FURTHER INFORMATION CONTACT: Sharron L. Gebhardt, Lead Regulatory Specialist, Chief of Staff Office, Minerals Revenue Management, MMS, telephone (303) 231–3211, fax (303) 231–3781.

The principal authors of this rule are Mary A. Williams, Kenneth R. Vogel, and James P. Morris of Minerals Revenue Management, MMS, and Martin C. Grieshaber of Policy and Management Improvement, MMS, and Geoffrey Heath of the Office of the Solicitor, Department of the Interior.

SUPPLEMENTARY INFORMATION:

I. Background

The MMS is amending the existing regulations at 30 CFR 206.100 *et seq.*, governing the valuation of crude oil produced from Federal leases for royalty purposes, and related provisions governing the reporting thereof. The current regulations became effective on June 1, 2000 (June 2000 Rule).

After conducting several public workshops, MMS issued a proposed rule that was published in the **Federal Register** on August 20, 2003 (64 FR 50088). The original comment period for this proposed rule closed on September 19, 2003. However, MMS received requests to extend the comment period and on September 26, 2003, MMS reopened the comment period until November 10, 2003 (68 FR 55556).

The amendments do not alter the basic structure or underlying principles of the June 2000 Rule. In proposing these amendments, the Department of the Interior reaffirmed that the value for royalty purposes of crude oil produced from Federal leases is the value at or near the lease. However, in determining value at the lease of production not sold under an arm's-length contract, MMS is not restricted to a comparison to arm's-length sales of other production occurring in the field or area. MMS may begin with a ''downstream'' price or value, and determine value at the lease by deducting the costs of transporting oil to downstream sales points or markets, or by making appropriate adjustments for location and quality.

Federal lessees are not obligated to sell crude oil downstream of the lease. Lessees are at liberty to sell production at or near the lease, even if selling downstream might have resulted in a higher royalty value for the production than selling it at the lease. If lessees do choose to sell downstream, the choice to sell downstream does not make otherwise non-deductible costs deductible (for example, marketing costs). *See Independent Petroleum Association of America, et al.* v. *DeWitt,* 279 F.3d 1036 (DC Cir. 2002), *cert. denied sub nom., Independent Petroleum Association of America, et al.* v. *Watson,* 537 U.S. 1105 (2003). In addition, MMS may choose to use downstream values when a lessee sells to an affiliate at or near the lease.

II. Comments on the Proposed Rule

Public comments received in response to the proposed rule favored most of the proposed changes. MMS received some negative comments regarding the proposed method for valuing California and Alaska crude oil, some of the specifications of allowable transportation costs, and changing the rate of return on undepreciated capital investments in calculating non-arms-length transportation allowances. We will group the comments received and the MMS responses generally according to the order of the substantive provisions of the rule (with related changes to definitions), with discussion of miscellaneous technical changes thereafter. MMS received comments on the proposed rule from 27 respondents.

A. Changing to NYMEX-Based Valuation and Determining the NYMEX Price To Use for Valuation—§ 206.103

MMS proposed using New York Mercantile Exchange (NYMEX)-based value with a roll as one of the measures of value for production not sold at arm's length in all areas except for California, Alaska, and the Rocky Mountain Region where MMS proposed to use NYMEX-based value without the roll. In the Rocky Mountain Region, NYMEX-based value without the roll would be used as the revised third benchmark (proposed to be redesignated as § 206.103(b)(3)). The base NYMEX price would be adjusted for location and quality differentials and actual transportation costs back to the lease.

Summary of Comments: Fifteen respondents submitted comments on the use of NYMEX pricing. There were several comments about our rationale for changing from a spot market index price to NYMEX and adjusting for