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Neil D. Schalekamp,
*Acting Manager, Transport Airplane
 Directorate, Aircraft Certification Service.*
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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

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 adds an age precaution to labeling for moxidectin gel used for the control of various species of internal parasites in horses and ponies.

DATES: This rule is effective August 27, 2003.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; tel: 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% Equine Oral Gel used for the control of various species of internal parasites in horses and ponies. The supplemental NADA adds a precaution to labeling that the product is for oral use in horses and ponies 6 months of age and older. The supplemental NADA is approved as of May 29, 2003, and the regulations are amended in 21 CFR 520.1452 to reflect the approval and to reflect current format. 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 Dockets Management Branch (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(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 paragraphs (a), (d)(3), and by adding paragraph (c) to read as follows:

§ 520.1452 Moxidectin gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (2 percent) moxidectin.

* * * * *

(c) *Special considerations.* See § 500.25 of this chapter.

(d) * * *

(3) *Limitations.* For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

Dated: August 13, 2003.

Steven D. Vaughn,
*Director, Office of New Animal Drug
 Evaluation, Center for Veterinary Medicine.*
 [FR Doc. 03-21834 Filed 8-27-03; 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; 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 a new animal drug application (NADA) filed by Fort Dodge Animal Health, Division of Wyeth. The NADA provides for use of a moxidectin and praziquantel oral gel for the treatment and control of various species of internal parasites in horses and ponies.

DATES: This rule is effective August 27, 2003.

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, Div. of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed NADA 141-216 for QUEST PLUS (moxidectin 2.0%/praziquantel 12.5%) Gel for the treatment and control of various species of internal parasites in horses and ponies. The NADA is approved as of May 14, 2003, and part 520 (21 CFR part 520) is amended by adding new § 520.1453 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 Dockets Management Branch (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.

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 520.1453 is added to read as follows:

§ 520.1453 Moxidectin and praziquantel gel.

(a) *Specifications.* Each milliliter of gel contains 20 milligrams (mg) (2.0 percent) moxidectin and 125 mg (12.5 percent) praziquantel.

(b) *Sponsor.* See No. 000856 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25 of this chapter.

(d) *Conditions of use in horses and ponies*—(1) *Amount.* Administer by mouth as a single dose: 0.4 mg moxidectin per kilogram and 2.5 mg praziquantel per kilogram (2.2 pounds) body weight.

(2) *Indications for use.* For treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adults and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cyathostomum catinatum* (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated luminal 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)); horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)); and tapeworms (*Anoplocephala perfoliata*

(adults)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* For oral use in horses and ponies 6 months of age and older. Not for use in horses and ponies intended for food.

Dated: August 13, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03–21833 Filed 8–26–03; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9075]

RIN 1545–AX52

Compensation Deferred Under Eligible Deferred Compensation Plans; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains final regulations that provide guidance on deferred compensation plans of state and local governments and tax-exempt entities. The regulations reflect the changes made to section 457 by the Tax Reform Act of 1986, the Small Business Job Protection Act of 1996, the Taxpayer Relief Act of 1997, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Job Creation and Worker Assistance Act of 2002, and other legislation. This document was published in the **Federal Register** on July 11, 2003 (68 FR 41230).

EFFECTIVE DATE: These final regulations are effective July 11, 2003.

FOR FURTHER INFORMATION CONTACT: Cheryl Press (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under sections 457 by the Tax Reform Act of 1986, the Small Business Job Protection Act of 1996, the Taxpayer Relief Act of 1997, the Economic Growth and Tax Relief Reconciliation Act of 2001, the Job Creation and Worker Assistance Act of 2002, and other legislation.

Need for Correction

As published, the final regulations (TD 9075) contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

■ Accordingly, the publication of the final regulations (TD 9075), which are the subject of FR Doc. 03–17523, is corrected as follows:

§ 1.457–2 [Corrected]

■ 1. On page 41235, column 2, § 1.457–2, paragraph (k), line 10, the language "treated as agreements or arrangement" is corrected to read "treated as agreements or arrangements".

■ 2. On page 41235, column 3, § 1.457–2, paragraph (i), line 5, the language "amended by section 1011(e)(6) of" is corrected to read "amended by section 1011(e)(6) of the".

■ 3. On page 41235, column 3, § 1.457–2, paragraph (ii), line 2, the language "nonelective deferred a compensation" is corrected to read "nonelective deferred compensation".

§ 1.457–4 [Corrected]

■ 4. On page 41236, column 2, § 1.457–4, paragraph (i), of *Example 1*, line 5, the language "compensation for that year. Participant A is" is corrected to read "compensation for that year. A is".

■ 5. On page 41236, column 3, § 1.457–4, paragraph (b)(ii), paragraph (i), of *Example 3*, line 3, the language "per year for five years to Participant B's" is corrected to read "per year for five years to B's".

■ 6. On page 41236, column 3, § 1.457–4, paragraph (i), of *Example 3*, lines 3 thru 7, the language "per year for five years to Participant B's eligible plan account. B's interest in the account vests in 2006. B has annual compensation of \$50,000 in each of the five years 2002 through 2006. Participant B is 41" is corrected to read "per year for five years to B's eligible plan account. B's interest in the account vests in 2006. B has annual compensation of \$50,000 in each of the five years 2002 through 2006. B is 41".

■ 7. On page 41236, column 3, § 1.457–4, paragraph (ii), of *Example 3*, line 6, the language "amounts deferred, \$17,000, is in excess of the" is corrected to read "amounts deferred, \$17,000, is in excess of".

§ 1.457–5 [Corrected]

■ 8. On page 41241, column 1, § 1.457–5, paragraph (i), of *Example 2*, the language "four eligible plans during 2006: Plan W" is corrected to read "four eligible plans during 2006 Plan W".

§ 1.457–6 [Corrected]

■ 9. On page 41242, column 2, § 1.457–6, paragraph (e)(2), third line from the bottom of the paragraph, the language "but allow participants or beneficiary