

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Mepivacaine**

**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 Pharmacia & Upjohn Co. The supplemental NADA provides for revised food safety labeling for mepivacaine injectable solution used in horses for local anesthesia.

**DATES:** This rule is effective July 13, 2006.

**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: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 100 703 for CARBOCAINE-V (mepivacaine hydrochloride) Sterile Aqueous Solution. The supplemental NADA provides for revised food safety labeling for mepivacaine injectable solution used in horses for local anesthesia. The application is approved as of June 2, 2006, and the regulations are amended in § 522.1372 (21 CFR 522.1372) to reflect the approval.

In addition, FDA has found that the April 1, 2005, edition of parts 500 to 599 of title 21 of the Code of Federal Regulations (CFR) does not accurately reflect the approved conditions of use for mepivacaine solution used in horses. These conditions of use were inadvertently deleted as a publication error. At this time, the regulations are being amended in § 522.1372 to correct this error and to format portions of this section to reflect a current format. This action is being taken to improve the accuracy of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under § 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 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. Revise § 522.1372 to read as follows:

**§ 522.1372 Mepivacaine.**

(a) *Specifications.* Each milliliter (mL) of solution contains 20 milligrams mepivacaine hydrochloride.

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses—(1) Amount.* For nerve block, 3 to 5 mL; for epidural anesthesia, 5 to 20 mL; for intra-articular anesthesia, 10 to 15 mL; for infiltration, as required; for anesthesia of the laryngeal mucosa prior to ventriculectomy, by topical spray, 25 to 40 mL, by infiltration, 20 to 50 mL.

(2) *Indications for use.* For use as a local anesthetic for infiltration, nerve block, intra-articular and epidural anesthesia, and topical and/or infiltration anesthesia of the laryngeal mucosa prior to ventriculectomy.

(3) *Limitations.* Not for use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: June 30, 2006.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. E6-10970 Filed 7-12-06; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 522****Implantation or Injectable Dosage Form New Animal Drugs; Furosemide**

**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 provides for the revision of a food safety warning on labeling of furosemide injectable solution for use in horses.

**DATES:** This rule is effective July 13, 2006.

**FOR FURTHER INFORMATION CONTACT:** Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: [melanie.berson@fda.hhs.gov](mailto:melanie.berson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed a supplement to NADA 34-478 for SALIX (furosemide) Injection 5%. The supplemental NADA provides for the revision of a food safety warning on labeling of furosemide injectable solution for use in horses. The supplemental application is approved as of June 20, 2006, and the regulations are amended in 21 CFR 522.1010 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(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 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 § 522.1010, revise paragraph (b)(3); and add paragraphs (b)(4) and (d)(2)(iii) to read as follows:

**§ 522.1010 Furosemide.**

\* \* \* \* \*

(b) \* \* \*

(3) No. 059130 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

(4) No. 057926 as described in paragraph (a)(2) for use as in paragraphs (d)(1), (d)(2)(iii), and (d)(3) of this section.

\* \* \* \* \*

(d) \* \* \*

(2) \* \* \*

(iii) *Amount.* 250 to 500 mg/animal once or twice daily, intramuscularly or intravenously.

(A) *Indications for use.* For the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency, and acute noninflammatory tissue edema.

(B) *Limitations.* Do not use in horses intended for human consumption.

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Dated: June 30, 2006.

**Steven D. Vaughn,**

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

[FR Doc. E6-10974 Filed 7-12-06; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9270]

RIN 1545-AW72

**Reporting of Gross Proceeds Payments to Attorneys**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations relating to the reporting of payments of gross proceeds to attorneys. The regulations reflect changes to the law made by the Taxpayer Relief Act of

1997 (1997 Act). The final regulations will affect attorneys who receive payments of gross proceeds on behalf of their clients and will affect certain payors (for example, defendants in lawsuits and their insurance companies and agents) that, in the course of their trades or businesses, make payments to these attorneys.

**DATES:** *Effective Dates:* These regulations are effective July 13, 2006.

*Applicability Dates:* For dates of applicability, see § 1.6045-5(h).

**FOR FURTHER INFORMATION CONTACT:**

Nancy Rose, (202) 622-4940 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Paperwork Reduction Act**

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-1644.

Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by September 11, 2006. Comments are specifically requested concerning:

Whether the collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collections of information in the final regulations are in §§ 1.6041-3(p) and 1.6045-5(a). Section 1021(a) of the 1997 Act added section 6045(f) to the Internal Revenue Code (Code) and requires the IRS to implement

information reporting of certain payments made to attorneys. Section 1021(b) of the 1997 Act provides that the exception to information reporting in the regulations under section 6041 for payments to corporations does not apply to payments to attorneys and requires the IRS to implement information reporting for payments to attorneys. This information will be used to verify compliance with sections 6045(f) and 6041 and to determine that the amount of these payments has been reported correctly. The collections of information are mandatory. The likely respondents (payors) are businesses and other for profit institutions.

Payors provide the information by completing Form 1099-MISC, "Miscellaneous Income," for each attorney who has received one or more payments aggregating \$600 or more from the payor during the calendar year. The burden for this requirement is reflected in the burden estimate for Form 1099-MISC. The estimated burden of information collection for the 2005 Form 1099-MISC is 16 minutes per return.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and return information are confidential, as required by 26 U.S.C. 6103.

**Background**

This document contains amendments to the 26 CFR part 1 under sections 6041 and 6045 of the (Code). These amendments to the Income Tax Regulations revise existing §§ 1.6041-1 and 1.6041-3 and add new § 1.6045-5. This document finalizes proposed regulations relating to information reporting under section 6045(f) of the Code for gross proceeds paid to attorneys. The proposed regulations were contained in a notice of proposed rulemaking (REG-126024-01) published in the **Federal Register** on May 17, 2002 (67 FR 35064).

Section 6045(f) was added to the Code by the 1997 Act (Pub. L. 105-34, section 1021 (111 Stat. 788)). Section 6045(f) generally requires information reporting for payments of gross proceeds made in the course of a trade or business to attorneys in connection with legal services (whether or not the services are