

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Pyrantel Pamoate Paste

**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 Phoenix Scientific, Inc. The NADA provides for the oral use of pyrantel pamoate paste for the removal and control of mature infections of tapeworms in horses and ponies.

**DATES:** This rule is effective May 23, 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: [melanie.berson@fda.gov](mailto:melanie.berson@fda.gov).

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed supplemental NADA 200-342 that provides for the use of Pyrantel Pamoate Paste for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*) in horses and ponies. The supplemental NADA is approved as of April 18, 2005, and the regulations are amended in 21 CFR 520.2044 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.

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 supplemental approval qualifies for 3 years of marketing exclusivity beginning April 18, 2005.

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 520.2044 is revised to read as follows:

##### § 520.2044 Pyrantel pamoate paste.

(a) *Specifications*—(1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).

(2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter.

(1) No. 000069 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

(2) No. 059130 for use of product described in paragraph (a)(2) of this section as in paragraph (d) of this section.

(3) No. 061623 for use of product described in paragraph (a)(3) of this section as in paragraph (d)(1)(i) and (d)(2) of this section.

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

(d) *Conditions of use*. It is used in horses and ponies as follows:

(1) *Amounts and indications for use*—(i) 3 mg per pound (/lb) body weight as single oral dose for removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

(ii) 6 mg/lb body weight as single oral dose for the removal and control of mature infections of tapeworms (*Anoplocephala perfoliata*).

(2) *Limitations*. Not for use in horses intended for food.

Dated: May 11, 2005.

**Steven D. Vaughn,**

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

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9204]

RIN 1545-BC59

#### Mortgage Revenue Bonds

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

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations that provide guidance regarding the limitation on the effective rate of mortgage interest for purposes of mortgage revenue bonds issued by State and local governments. These regulations provide guidance to State and local governments that issue tax-exempt mortgage revenue bonds.

**DATES:** *Effective Date:* These regulations are effective May 23, 2005.

*Applicability Date:* For dates of applicability, see § 1.143(g)-1(d) of these regulations.

**FOR FURTHER INFORMATION CONTACT:**

Michael P. Brewer, (202) 622-3980 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

#### Background

This document amends the Income Tax Regulations (26 CFR part 1) under section 143(g) of the Internal Revenue Code by providing rules regarding the limitation on the effective rate of mortgage interest for purposes of mortgage revenue bonds issued by State and local governments. On November 5, 2003, the IRS published in the **Federal Register** a notice of proposed rulemaking (REG-146692-03)(68 FR 62549)(the proposed regulations). The proposed regulations would add § 1.143(g)-1 to provide rules for calculating the effective rate of mortgage interest. A public hearing on the proposed regulations was scheduled for January 28, 2004. The public hearing was cancelled because no requests to speak were received. Written comments were received regarding the proposed regulations. After consideration of the written comments, the proposed regulations are adopted by this Treasury decision without change (other than

certain clarifying changes to the effective date provisions).

#### *A. Mortgage Revenue Bonds*

Section 103(a) of the Internal Revenue Code of 1986 (Code) provides that, generally, interest on any State or local bond is not included in gross income. However, this exclusion does not apply to any private activity bond that is not a qualified bond.

Section 141(e)(1) provides that a qualified mortgage bond or a qualified veterans' mortgage bond (together, mortgage revenue bonds) issued under section 143 may be a qualified bond.

Sections 143(a)(2)(A)(ii) and 143(b) provide, in part, that for an issue to be an issue of qualified mortgage bonds or qualified veterans' mortgage bonds, respectively, the issue must satisfy the requirements of section 143(g). Section 143(g)(1) provides that an issue will meet the requirements of section 143(g) if the issue satisfies the requirements of section 143(g)(2) and, in the case of an issue 95 percent or more of the net proceeds of which are to be used to provide residences for veterans, if the issue satisfies the requirements of section 143(g)(3).

Section 143(g)(2)(A) provides that an issue will meet the requirements of section 143(g)(2) only if the excess of (1) the effective interest rate on the mortgages provided under the issue, over (2) the yield on the issue, is not greater than 1.125 percentage points.

Section 143(g)(2)(B)(i) provides that in determining the effective rate of interest on any mortgage for purposes of section 143(g)(2), all fees, charges, and other amounts borne by the mortgagor that are attributable to the mortgage or the bond issue are taken into account as additional interest paid.

Section 143(g)(2)(B)(ii) provides that, for purposes of determining the effective rate of mortgage interest, the following items (among others) shall be treated as borne by the mortgagor: (1) All points or similar charges paid by the seller of the property; and (2) the excess of the amounts received from any person other than the mortgagor by any person in connection with the acquisition of the mortgagor's interest in the property over the usual and reasonable acquisition costs of a person acquiring like property when owner-financing is not provided through the use of mortgage revenue bonds.

Section 143(g)(2)(B)(iii) provides that, for purposes of determining the effective rate of mortgage interest, the following items shall not be taken into account: (1) Any expected rebate of arbitrage profits; and (2) any application fee, survey fee, credit report fee, insurance charge, or

similar amount to the extent such amount does not exceed amounts charged in such area in cases when owner-financing is not provided through the use of mortgage revenue bonds. The exclusion for application fees, survey fees, credit report fees, insurance charges, or similar amounts does not apply to origination fees, points, or similar amounts.

In the case of an issue 95 percent or more of the net proceeds of which are to be used to provide residences for veterans, section 143(g)(3) provides that certain earnings on nonpurpose investments must either be paid or credited to mortgagors, or paid to the United States, in certain circumstances.

In the Tax Reform Act of 1986, Public Law 99-514 (the 1986 Act), Congress reorganized sections 103 and 103A of the Internal Revenue Code of 1954 (1954 Code) regarding tax-exempt bonds into sections 103 and 141 through 150 of the Code. Congress intended that to the extent not amended by the 1986 Act, all principles of pre-1986 Act law would continue to apply to the reorganized provisions. 2 H.R. Conf. Rep. No. 841, 99th Cong., 2d Sess. II-686 (1986), 1986-3 (Vol. 4) C.B. 686.

Interpreting section 103A(i)(2)(B)(iii) of the 1954 Code, which is substantially identical to section 143(g)(2)(B)(iii) of the Code, § 6a.103A-2(i)(2)(ii)(C) of the Temporary Income Tax Regulations provides the following: "For example, amounts paid for FHA, VA, or similar private mortgage insurance on an individual's mortgage need not be taken into account so long as such amounts do not exceed the amounts charged in the area with respect to a similar mortgage that is not financed with qualified mortgage bonds. Premiums charged for pool mortgage insurance will be considered amounts in excess of the usual and reasonable amounts charged for insurance in cases where owner financing is not provided through the use of qualified mortgage bonds." Pool mortgage insurance is not defined in the regulations.

#### *B. Qualified Guarantees*

Under § 1.148-4(f), for purposes of computing yield on an issue, fees paid for a qualified guarantee for the issue are treated as additional interest on the issue. In general, a guarantee is a qualified guarantee if: (1) As of the date the guarantee is obtained, the issuer reasonably expects that the present value of the fees for the guarantee will be less than the present value of the expected interest savings on the issue as a result of the guarantee; (2) the arrangement creates a guarantee in substance; and (3) the fees for the

guarantee do not exceed a reasonable, arm's-length charge for the transfer of credit risk. The regulations provide that the guarantee of a loan of proceeds of an issue, as opposed to a guarantee of the issue, may constitute a qualified guarantee, but this rule does not apply to guarantees of mortgages financed with mortgage revenue bonds.

#### **Explanation of Provisions**

##### *A. Pool Mortgage Insurance*

Prior to the issuance of the proposed regulations, questions arose regarding whether an issuer should be required to treat the portion of the interest payments on a pool of mortgages used to pay fees for a guarantee of a pass-through security backed by the pool of mortgages as an amount borne by the mortgagors that must be taken into account in determining the effective rate of interest on the mortgages for purposes of section 143(g). Taking the guarantee fees into account results in a higher effective rate of interest on the mortgages than if the fees were not taken into account.

The IRS and Treasury Department have determined that the guarantee fees should not be treated as amounts borne by the mortgagors that must be taken into account in determining the effective rate of interest on the mortgages for purposes of section 143(g). An issuer may achieve substantially the same result as not taking the guarantee fees into account in computing the effective rate of interest on the mortgages by substituting a qualified guarantee on the bonds for the guarantee of the pool of mortgages. If an issuer does not take the mortgage guarantee fees into account in computing the effective rate of interest on the mortgages, the difference between the bond yield and the effective rate on the mortgages is reduced because the effective rate on the mortgages is reduced. A qualified guarantee of the bonds accomplishes the same result by increasing bond yield, rather than reducing the effective rate of interest on the mortgages. Issuers should not be required to change the form of their transactions in these circumstances.

Accordingly, to the extent the amounts charged for a guarantee of a pool of mortgages do not exceed amounts charged in the area in cases when owner-financing is not provided through the use of mortgage revenue bonds, the proposed regulations would provide that such amounts are not treated as borne by the mortgagors and are not taken into account in determining the effective rate of interest

on the mortgages for purposes of section 143(g).

### *B. Proposed Regulations*

The proposed regulations propose a new § 1.143(g)–1. The proposed regulations provide that an issue satisfies the requirements of section 143(g) only if the issue meets the requirements of § 1.143(g)–1(b) and, in the case of an issue 95 percent or more of the net proceeds of which are to be used to provide residences for veterans, the issue also meets the requirements of § 1.143(g)–1(c). The requirements of section 143(g) and the proposed regulations are applicable in addition to the requirements of section 148 and §§ 1.148–0 through 1.148–11.

The proposed regulations provide that an issue shall be treated as meeting the requirements of § 1.143(g)–1(b) only if the excess of (1) the effective rate of interest on the mortgages financed by the issue, over (2) the yield on the issue, is not greater over the term of the issue than 1.125 percentage points.

In determining the effective rate of interest on any mortgage, the proposed regulations provide that all fees, charges, and other amounts borne by the mortgagor that are attributable to the mortgage or to the bond issue are taken into account. Such amounts include points, commitment fees, origination fees, servicing fees, and prepayment penalties paid by the mortgagor.

The proposed regulations provide that items that are treated as borne by the mortgagor and are taken into account in calculating the effective rate of interest also include: (1) All points, commitment fees, origination fees, or similar charges borne by the seller of the property; and (2) the excess of any amounts received from any person other than the mortgagor by any person in connection with the acquisition of the mortgagor's interest in the property over the usual and reasonable acquisition costs of a person acquiring like property where owner-financing is not provided through the use of mortgage revenue bonds.

The proposed regulations further provide that the following items are not treated as borne by the mortgagor and are not taken into account in calculating the effective rate of interest: (1) Any expected rebate of arbitrage profit; and (2) any application fee, survey fee, credit report fee, insurance charge or similar settlement or financing cost to the extent such amount does not exceed amounts charged in the area in cases where owner-financing is not provided through the use of mortgage revenue bonds.

With respect to insurance charges, the proposed regulations provide that amounts paid for Federal Housing Administration, Veterans' Administration, or similar private mortgage insurance on an individual's mortgage, or amounts paid for pool mortgage insurance on a pool of mortgages, are not taken into account so long as such amounts do not exceed the amounts charged in the area with respect to a similar mortgage, or pool of mortgages, that is not financed with mortgage revenue bonds. Moreover, for this purpose, amounts paid for pool mortgage insurance include amounts paid to an entity (for example, the Government National Mortgage Association, the Federal National Mortgage Association, the Federal Home Loan Mortgage Corporation, or other mortgage insurer) to directly guarantee the pool of mortgages financed with the bonds, or to guarantee a pass-through security backed by the pool of mortgages financed with the bonds.

The proposed regulations do not provide guidance regarding all aspects of the application of section 143(g)(2). The proposed regulations provide that to the extent not inconsistent with the 1986 Act or subsequent law, the provisions of § 6a.103A–2(i)(2) (other than paragraphs (i)(2)(i) and (i)(2)(ii)(A) through (C)) apply to provide additional rules relating to compliance with the requirement that the effective rate of mortgage interest not exceed the bond yield by more than 1.125 percentage points.

The proposed regulations also do not provide guidance regarding the application of section 143(g)(3). The proposed regulations provide that to the extent not inconsistent with the 1986 Act or subsequent law, the provisions of § 6a.103A–2(i)(4) apply to provide guidance regarding the application of section 143(g)(3).

### *C. Final Regulations*

All of the public comments expressed support for the proposed regulations as proposed, and the proposed regulations are adopted by this Treasury decision without change other than certain changes to the effective date provisions to reflect that the regulations are being issued in final form.

### **Effective Dates**

The final regulations apply to bonds sold on or after May 23, 2005, that are subject to section 143. Issuers may apply the final regulations in whole, but not in part, to bonds sold before May 23, 2005, that are subject to section 143. Subject to the applicable effective dates for the corresponding statutory

provisions, issuers may apply the final regulations, in whole, but not in part, to bonds that are subject to section 103A(i) of the Internal Revenue Code of 1954. To the extent that an issuer applies the final regulations to bonds that were issued before July 1, 1993, § 6a.103A–2(i)(3) also applies.

### **Special Analyses**

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

### **Drafting Information**

The principal authors of these regulations are Timothy L. Jones and Michael P. Brewer, Office of Associate Chief Counsel (Tax-exempt and Government Entities), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

### **List of Subjects in 26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

### **Adoption of Amendments to the Regulations**

■ Accordingly, 26 CFR part 1 is amended as follows:

### **PART 1—INCOME TAXES**

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

**Authority:** 26 U.S.C. 7805 \* \* \*

■ **Par. 2.** Section 1.143(g)–1 is added to read as follows:

#### **§ 1.143(g)–1 Requirements related to arbitrage.**

(a) *In general.* Under section 143, for an issue to be an issue of qualified mortgage bonds or qualified veterans' mortgage bonds (together, mortgage revenue bonds), the requirements of section 143(g) must be satisfied. An issue satisfies the requirements of section 143(g) only if such issue meets the requirements of paragraph (b) of this

section and, in the case of an issue 95 percent or more of the net proceeds of which are to be used to provide residences for veterans, such issue also meets the requirements of paragraph (c) of this section. The requirements of section 143(g) and this section are applicable in addition to the requirements of section 148 and §§ 1.148-0 through 1.148-11.

(b) *Effective rate of mortgage interest not to exceed bond yield by more than 1.125 percentage points*—(1) *Maximum yield*. An issue shall be treated as meeting the requirements of this paragraph (b) only if the excess of the effective rate of interest on the mortgages financed by the issue, over the yield on the issue, is not greater over the term of the issue than 1.125 percentage points.

(2) *Effective rate of interest*. (i) In determining the effective rate of interest on any mortgage for purposes of this paragraph (b), there shall be taken into account all fees, charges, and other amounts borne by the mortgagor that are attributable to the mortgage or to the bond issue. Such amounts include points, commitment fees, origination fees, servicing fees, and prepayment penalties paid by the mortgagor.

(ii) Items that shall be treated as borne by the mortgagor and shall be taken into account in calculating the effective rate of interest also include—

(A) All points, commitment fees, origination fees, or similar charges borne by the seller of the property; and

(B) The excess of any amounts received from any person other than the mortgagor by any person in connection with the acquisition of the mortgagor's interest in the property over the usual and reasonable acquisition costs of a person acquiring like property when owner-financing is not provided through the use of mortgage revenue bonds.

(iii) The following items shall not be treated as borne by the mortgagor and shall not be taken into account in calculating the effective rate of interest—

(A) Any expected rebate of arbitrage profit under paragraph (c) of this section; and

(B) Any application fee, survey fee, credit report fee, insurance charge or similar settlement or financing cost to the extent such amount does not exceed amounts charged in the area in cases when owner-financing is not provided through the use of mortgage revenue bonds. For example, amounts paid for Federal Housing Administration, Veterans' Administration, or similar private mortgage insurance on an individual's mortgage, or amounts paid

for pool mortgage insurance on a pool of mortgages, are not taken into account so long as such amounts do not exceed the amounts charged in the area with respect to a similar mortgage, or pool of mortgages, that is not financed with mortgage revenue bonds. For this purpose, amounts paid for pool mortgage insurance include amounts paid to an entity (for example, the Government National Mortgage Association, the Federal National Mortgage Association (FNMA), the Federal Home Loan Mortgage Corporation, or other mortgage insurer) to directly guarantee the pool of mortgages financed with the bonds, or to guarantee a pass-through security backed by the pool of mortgages financed with the bonds.

(C) The following example illustrates the provisions of this paragraph (b)(2)(iii):

*Example*. Housing Authority X issues bonds intended to be qualified mortgage bonds under section 143(a). At the time the bonds are issued, X enters into an agreement with a group of mortgage lending institutions (lenders) under which the lenders agree to originate and service mortgages that meet certain specified requirements. After originating a specified amount of mortgages, each lender issues a "pass-through security" (each, a PTS) backed by the mortgages and sells the PTS to X. Under the terms of the PTS, the lender pays X an amount equal to the regular monthly payments on the mortgages (less certain fees), whether or not received by the lender (plus any prepayments and liquidation proceeds in the event of a foreclosure or other disposition of any mortgages). FNMA guarantees the timely payment of principal and interest on each PTS. From the payments received from each mortgagor, the lender pays a fee to FNMA for its guarantee of the PTS. The amounts paid to FNMA do not exceed the amounts charged in the area with respect to a similar pool of mortgages that is not financed with mortgage revenue bonds. Under this paragraph (b)(2)(iii), the fees for the guarantee provided by FNMA are an insurance charge because the guarantee is pool mortgage insurance. Because the amounts charged for the guarantee do not exceed the amounts charged in the area with respect to a similar pool of mortgages that is not financed with mortgage revenue bonds, the amounts charged for the guarantee are not taken into account in computing the effective rate of interest on the mortgages financed with X's bonds.

(3) *Additional rules*. To the extent not inconsistent with the Tax Reform Act of 1986, Public Law 99-514 (the 1986 Act), or subsequent law, § 6a.103A-2(i)(2) (other than paragraphs (i)(2)(i) and (i)(2)(ii)(A) through (C)) of this chapter applies to provide additional rules relating to compliance with the requirement that the effective rate of mortgage interest not exceed the bond

yield by more than 1.125 percentage points.

(c) *Arbitrage and investment gains to be used to reduce costs of owner-financing*. As provided in section 143(g)(3), certain earnings on nonpurpose investments must either be paid or credited to mortgagors, or paid to the United States, in certain circumstances. To the extent not inconsistent with the 1986 Act or subsequent law, § 6a.103A-2(i)(4) of this chapter applies to provide guidance relating to compliance with this requirement.

(d) *Effective dates*—(1) *In general*. Except as otherwise provided in this section, § 1.143(g)-1 applies to bonds sold on or after May 23, 2005, that are subject to section 143.

(2) *Permissive retroactive application in whole*. Except as provided in paragraph (d)(4) of this section, issuers may apply § 1.143(g)-1, in whole, but not in part, to bonds sold before May 23, 2005, that are subject to section 143.

(3) *Bonds subject to the Internal Revenue Code of 1954*. Except as provided in paragraph (d)(4) of this section and subject to the applicable effective dates for the corresponding statutory provisions, an issuer may apply § 1.143(g)-1, in whole, but not in part, to bonds that are subject to section 103A(i) of the Internal Revenue Code of 1954.

(4) *Special rule for pre-July 1, 1993 bonds*. To the extent that an issuer applies this section to bonds issued before July 1, 1993, § 6a.103A-2(i)(3) of this chapter also applies to the bonds.

**Mark E. Matthews,**

*Deputy Commissioner for Services and Enforcement.*

Approved: May 12, 2005.

**Eric Solomon,**

*Acting Deputy Assistant Secretary of the Treasury.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1 and 602

[TD 9206]

RIN 1545-BE12

#### Information Returns by Donees Relating to Qualified Intellectual Property Contributions

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

**ACTION:** Temporary regulations.