

**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 Phoenix Scientific, Inc. The ANADA provides for use of tiamulin soluble powder to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia.

**DATES:** This rule is effective March 18, 2005.

**FOR FURTHER INFORMATION CONTACT:**

Daniel A. Benz, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: [daniel.benz@fda.gov](mailto:daniel.benz@fda.gov).

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200-344 that provides for use of Tiamulin Soluble Antibiotic to prepare medicated drinking water for the treatment of swine dysentery and swine pneumonia. Phoenix Scientific, Inc.'s Tiamulin Soluble Antibiotic is approved as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s DENAGARD (tiamulin) Soluble Antibiotic approved under NADA 134-644. The ANADA is approved as of February 16, 2005, and the regulations are amended in 21 CFR 520.2455 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

FDA is also amending the regulations in 21 CFR 520.2455 to reflect a more recent genus name for the causative pathogen for swine dysentery and in the tables in 21 CFR 510.600(c) to reflect accepted style for the sponsor's street address. These actions are being taken to improve the accuracy of the regulations.

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 Subjects**

*21 CFR Part 510*

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

*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 parts 510 and 520 are amended as follows:

**PART 510—NEW ANIMAL DRUGS**

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

**§ 510.600 [Amended]**

■ 2. Section 510.600 is amended in the table in paragraph (c)(1) in the entry for "Phoenix Scientific, Inc." and in the table in paragraph (c)(2) in the entry for "059130" by removing "St. Terrace" and by adding in its place "Street Ter."

**PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** 21 U.S.C. 360b.

**§ 520.2455 [Amended]**

■ 4. Section 520.2455 is amended in paragraph (b) by removing "Sponsor. See No. 000010" and by adding in its place "Sponsors. See Nos. 000010 and 059130"; and in paragraph (d)(1)(i) by removing "Treponema" and by adding in its place "Brachyspira".

Dated: March 9, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*  
[FR Doc. 05-5380 Filed 3-17-05; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 573**

**Food Additives Permitted in Feed and Drinking Water of Animals; Poly(2-vinylpyridine-co-styrene); Salts of Volatile Fatty Acids**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal food additive regulations to correct the specifications for two food additives used in cattle feed. Incorrect symbols describing permitted levels of heavy metals such as lead and arsenic are being corrected with text to reflect the maximum permitted levels of these two impurities in these food additives. This action is being taken to improve the accuracy of the agency's regulations.

**DATES:** This rule is effective March 18, 2005.

**FOR FURTHER INFORMATION CONTACT:**

Sharon Benz, Center for Veterinary Medicine (HFV-220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6864, e-mail: [sbenz@cvm.fda.gov](mailto:sbenz@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** FDA has found that part 573 (21 CFR part 573) of the Code of Federal Regulations does not accurately reflect the approved specifications for two food additives used in cattle feed, poly(2-vinylpyridine-co-styrene) and salts of volatile fatty acids. The greater than symbols in the tables describing the permitted levels of heavy metals such as lead and arsenic were incorrect. FDA is amending the regulations in §§ 573.870 and 573.914 to correctly reflect the maximum permitted levels of these two impurities in these food additives. This action is being taken to improve the accuracy of the agency's regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

**List of Subjects in 21 CFR 573**

Animal feeds, Food additives.

■ 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 573 is amended as follows:

**PART 573—FOOD ADDITIVES  
PERMITTED IN FEED AND DRINKING  
WATER OF ANIMALS**

■ 1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

■ 2. Section 573.870 is amended in paragraph (a) in the table by revising the entries for “Heavy metals such as lead” and “Arsenic” to read as follows:

**§ 573.870 Poly(2-vinylpyridine-co-styrene).**

\* \* \* \* \*

(a) \* \* \*

| Component/property        | Limitation                    |
|---------------------------|-------------------------------|
| * * *                     | * * *                         |
| Heavy metals such as lead | 10 parts per million maximum. |
| Arsenic                   | 3 parts per million maximum.  |

\* \* \* \* \*

■ 3. Section 573.914 is amended in the tables in paragraphs (b)(1) and (b)(2) by revising the entries for “Arsenic” and “Heavy metals as lead” to read as follows:

**§ 573.914 Salts of volatile fatty acids.**

\* \* \* \* \*

(b) \* \* \*

(1) \* \* \*

| Components                | Amount                        |
|---------------------------|-------------------------------|
| * * *                     | * * *                         |
| Arsenic                   | 3 parts per million maximum.  |
| Heavy metals such as lead | 10 parts per million maximum. |

(2) \* \* \*

| Components                | Amount                        |
|---------------------------|-------------------------------|
| * * *                     | * * *                         |
| Arsenic                   | 3 parts per million maximum.  |
| Heavy metals such as lead | 10 parts per million maximum. |

\* \* \* \* \*

Dated: March 8, 2005.

**Stephen F. Sundlof,**

Director, Center for Veterinary Medicine.

[FR Doc. 05-5344 Filed 3-17-05; 8:45 am]

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9191]

RIN 1545-BD16

**Time and Manner of Making Section 163(d)(4)(B) Election To Treat Qualified Dividend Income as Investment Income**

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

**ACTION:** Final regulations and removal of temporary regulations.

**SUMMARY:** This document contains final regulations relating to an election that may be made by noncorporate taxpayers to treat qualified dividend income as investment income for purposes of calculating the deduction for investment interest. The regulations reflect changes to the law made by the Jobs and Growth Tax Relief Reconciliation Act of 2003. The regulations affect taxpayers making the election under section 163(d)(4)(B) to treat qualified dividend income as investment income.

**DATES:** *Effective Date:* These regulations are effective March 18, 2005.

*Applicability Dates:* For dates of applicability, see § 1.163(d)-1(d).

**FOR FURTHER INFORMATION CONTACT:**

Amy Pfalzgraf, (202) 622-4950 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

This document contains amendments to 26 CFR part 1 under section 163(d) of the Internal Revenue Code (Code). On August 5, 2004, temporary regulations (TD 9147) were published in the **Federal Register** (69 FR 47364) relating to an election that may be made by noncorporate taxpayers to treat qualified dividend income as investment income for purposes of calculating the deduction for investment interest. A notice of proposed rulemaking (REG-171386-03) cross-referencing the temporary regulations also was published in the **Federal Register** (69 FR 47395) on August 5, 2004. No comments in response to the notice of proposed rulemaking or requests to speak at a public hearing were received, and no hearing was held. This Treasury decision adopts the proposed regulations and removes the temporary regulations.

**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 also has 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 proposed regulations preceding these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

**Drafting Information**

The principal author of these regulations is Amy Pfalzgraf of the Office of Associate Chief Counsel (Income Tax & Accounting). 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 1.163(d)-1 is revised to read as follows:

**§ 1.163(d)-1 Time and manner for making elections under the Omnibus Budget Reconciliation Act of 1993 and the Jobs and Growth Tax Relief Reconciliation Act of 2003.**

(a) *Description.* Section 163(d)(4)(B)(iii), as added by section 13206(d) of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66, 107 Stat. 467), allows an electing taxpayer to take all or a portion of certain net capital gain attributable to dispositions of property held for investment into account as investment income. Section 163(d)(4)(B), as amended by section 302(b) of the Jobs and Growth Tax Relief Reconciliation Act of 2003 (Pub. L. 108-27, 117 Stat. 762), allows an electing taxpayer to take all or a portion of qualified dividend income, as defined in section 1(h)(11)(B), into account as investment income. As a consequence, the net capital gain and qualified dividend