

pounds deducted from the possession limit for the additional trip. The Regional Administrator will issue this authorization automatically, without request from the vessel owner. A rebated possession limit may be combined with other additional trips as described in paragraph (c)(5)(ii) of this section.

\* \* \* \* \*

[FR Doc. 05-16613 Filed 8-19-05; 8:45 am]

BILLING CODE 3510-22-S

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Flunixin

**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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for veterinary prescription use of flunixin meglumine solution by intravenous injection in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia.

**DATES:** This rule is effective August 22, 2005.

**FOR FURTHER INFORMATION CONTACT:** John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9808, e-mail: [john.harshman@fda.gov](mailto:john.harshman@fda.gov).

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplemental ANADA 200 124 that provides for veterinary prescription use of Flunixin Meglumine Injection intravenously in lactating dairy cattle for control of fever associated with bovine respiratory disease and endotoxemia, and for control of inflammation in endotoxemia. The supplemental ANADA is approved as of July 18, 2005, and the regulations are amended in 21 CFR 522.970 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.

FDA 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 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. Section 522.970 is amended by revising paragraph (e)(2)(iii) to read as follows:

#### § 522.970 Flunixin.

\* \* \* \* \*

(e) \* \* \*

(2) \* \* \*

(iii) *Limitations.* Do not slaughter for food use within 4 days of last treatment. A withdrawal period has not been established for use in prurminating calves. Do not use in calves to be processed for veal. For Nos. 000061 and 059130: Do not use in dry dairy cows. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. For Nos. 055529 and 057561: Not for use in lactating or dry dairy cows.

Dated: August 10, 2005.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 05-16499 Filed 8-19-05; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9220]

RIN 1545-BE66

#### Converting an IRA Annuity to a Roth IRA

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

**ACTION:** Temporary Regulations.

**SUMMARY:** This document contains temporary regulations under section 408A of the Internal Revenue Code (Code). These temporary regulations provide guidance concerning the tax consequences of converting a non-Roth IRA annuity to a Roth IRA. These temporary regulations affect individuals establishing Roth IRAs, beneficiaries under Roth IRAs, and trustees, custodians and issuers of Roth IRAs. The text of these temporary regulations also serves as the text of proposed regulations set forth in a notice of proposed rulemaking in the Proposed Rules section of this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective August 19, 2005.

*Applicability Date:* These regulations are applicable to any Roth IRA conversion where an annuity contract is distributed or treated as distributed from a traditional IRA on or after August 19, 2005.

**FOR FURTHER INFORMATION CONTACT:** Concerning the regulations, Cathy A. Vohs, 202-622-6060.

#### SUPPLEMENTARY INFORMATION:

##### Background

##### *Roth IRAs and Conversions*

This document contains temporary regulations that amend the Income Tax Regulations (26 CFR part 1) under section 408A of Code relating to Roth IRAs. Section 408A of the Code, which was added by section 302 of the Taxpayer Relief Act of 1997, Public Law 105-34 (111 Stat. 788), establishes the Roth IRA as a type of individual retirement plan, effective for taxable years beginning on or after January 1, 1998.

Under Code section 408A, a Roth IRA is treated like a traditional IRA with several significant exceptions. Like amounts held in traditional IRAs, amounts held in Roth IRAs generally are exempt from Federal income tax under Code section 408(e)(1). Likewise, contributions to traditional IRAs and