DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin Tablets and Chewables

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for veterinary prescription use of chewable ivermectin tablets in dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection.

DATES: This rule is effective July 22, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–297 that provides for veterinary prescription use of Ivermectin Chewable Tablets for Dogs to prevent canine heartworm disease by eliminating the tissue stage of heartworm larvae (*Dirofilaria immitis*) for 1 month (30 days) after infection. Phoenix Scientific, Inc.'s Ivermectin Chewable Tablets for Dogs are approved as a generic copy of Merial Ltd.'s HEARTGARD Chewables, approved under NADA 140–886. The ANADA is approved as of June 18, 2004, and the regulations are amended in 21 CFR 520.1193 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.

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 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.

§ 520.1193 [Amended]

■ 2. Section 520.1193 is amended in paragraph (b)(2) by removing ''No. 051311'' and by adding in its place ''Nos. 051311 and 059130''.

Dated: July 13, 2004.

Stephen Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 04–16627 Filed 7–21–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9142]

RIN 1545–BB58

Deemed IRAs in Qualified Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations providing guidance under section 408(q) regarding accounts or annuities that are part of qualified employer plans but are to be treated as individual retirement plans. These regulations reflect changes made to the law by the Economic Growth and Tax Relief Reconciliation Act of 2001 and by the Job Creation and Worker Assistance Act of 2002. This document also contains temporary regulations under section 408(a) providing a special rule for governmental units seeking approval to serve as nonbank trustees of individual retirement accounts for purposes of section 408(q). These regulations affect administrators of, participants in, and beneficiaries of qualified employer plans.

DATES: *Effective Date:* These regulations are effective July 22, 2004.

Applicability Dates: For dates of applicability, see §§ 1.408(q)–1(i) and 1.408–2T(e)(8)(iv).

FOR FURTHER INFORMATION CONTACT: Linda Conway at (202) 622–6090 (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) under control number 1545–1841. Responses to this collection of information are required for taxpayers who want to include individual retirement plans as part of a qualified employer plan.

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

The estimated annual burden per respondent/recordkeeper is 50 hours.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be sent to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224, and 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.

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 tax return information are confidential, as required by 26 U.S.C. 6103.

Background

This document contains amendments to the Income Tax Regulations (26 CFR Part 1) under section 408(q) of the Internal Revenue Code (Code). On May 20, 2003, a notice of proposed rulemaking (REG–157302–02) was published in the **Federal Register** (68