

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 Pharmacia & Upjohn Co., a Div. of Pfizer, Inc. The supplemental NADA provides for the use of lincomycin in feed of swine weighing greater than 250 pounds and for the addition of a reproductive cautionary statement to labeling.

DATES: This rule is effective June 18, 2007.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Div. of Pfizer, Inc., 235 E. 42d St., New York, NY 10017, filed a supplement to NADA 97-505 that provides for use of LINCOMIX 20 (lincomycin hydrochloride) and LINCOMIX 50 Feed Medications in single-ingredient Type B and Type C medicated feeds for swine weighing greater than 250 pounds and for the addition of a reproductive caution statement to labeling. The supplemental application is approved as of May 23, 2007, and the regulations are amended in 21 CFR 558.325 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 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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

- 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

- 2. In § 558.325, add paragraph (c) and in the table in paragraphs (d)(2)(i) through (d)(2)(iv), in the "Limitations" column, remove "Not to be fed to swine that weigh more than 250 lb." wherever it occurs to read as follows:

§ 558.325 Lincomycin.

* * * * *

(c) Special considerations—(1)

Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin shall bear the following directions: "CAUTION: Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects."

(2) Labeling of Type A medicated articles and Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions: "CAUTION: Occasionally, swine fed lincomycin may within the first 2 days after the onset of treatment develop diarrhea and/or swelling of the anus. On rare occasions, some pigs may show reddening of the skin and irritable behavior. These conditions have been self-correcting within 5 to 8 days without discontinuing the lincomycin treatment."

(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following directions:

(i) No. 000009: "CAUTION: The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed."

(ii) Nos. 043733 and 051311: "CAUTION: Not to be fed to swine that weigh more than 250 lb."

* * * * *

Dated: June 8, 2007.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. E7-11611 Filed 6-15-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9331]

RIN 1545-BG46

Deemed IRAs in Governmental Plans/Qualified Nonbank Trustee Rules

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations under section 408 of the Internal Revenue Code. The final regulations provide special rules for a governmental unit which seeks to qualify as a nonbank trustee of a deemed IRA that is part of its qualified employer plan. These final regulations affect only such governmental units.

DATES: Effective Date: June 18, 2007.

Applicability Date: For dates of applicability, see § 1.408-2(e)(8)(iv).

FOR FURTHER INFORMATION CONTACT: Linda L. Conway, 202-622-6090, or Cathy A. Vohs, 202-622-6090 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains final amendments to the Income Tax Regulations (26 CFR Part 1) under section 408 of the Internal Revenue Code of 1986 (Code). On July 22, 2004, temporary and proposed regulations under section 408 were issued. A notice of proposed rulemaking (REG-101447-04) was published in the **Federal Register** (69 FR 43786). The text of the temporary regulations also served as the text of the proposed regulations. The text of temporary § 1.408-2(e)(8) was published in the same issue of the **Federal Register** (69 FR 43735). The RIN published in connection with that notice of proposed rulemaking was 1545-BD07. However, due to technical difficulties that RIN is no longer valid and the RIN number of these final regulations is 1545-BG46. No comments were received regarding the proposed regulations.

Explanation of Provisions and Summary of Comments

These final regulations amend § 1.408-2(e) of the regulations to provide that a governmental unit may serve as the trustee of any deemed IRA established by that governmental unit as part of its qualified employer plan if that governmental unit establishes to the

satisfaction of the Commissioner that the manner in which it will administer the deemed IRA will be consistent with the requirements of section 408. These final regulations also provide special rules regarding the application of § 1.408–2(e) to governmental units. These final regulations are adopted without substantive change from the proposed and temporary regulations. These final regulations are applicable for written applications made on or after June 18, 2007. The rules in this section also may be relied on for applications submitted on or after August 1, 2003 (or such earlier application as the Commissioner deems appropriate) and before June 18, 2007.

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 regulation does 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 final 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 author of these regulations is Linda L. Conway of the Office of the Division Counsel/Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and Treasury Department participated in the development of these regulations.

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 1.408–2(e)(8) is revised to read as follows:

§ 1.408–2 Individual retirement accounts.

* * * * *

(e) * * *

(8) *Special rules for governmental units*—(i) *In general.* A governmental unit that seeks to qualify as a nonbank trustee of a deemed IRA that is part of its qualified employer plan must demonstrate to the satisfaction of the Commissioner that it is able to administer the trust in a manner that is consistent with the requirements of section 408. The demonstration must be made by written application to the Commissioner. Notwithstanding the requirement of paragraph (e)(1) of this section that a person must demonstrate by written application that the requirements of paragraphs (e)(2) through (e)(6) of this section will be met in order to qualify as a nonbank trustee, a governmental unit that maintains a plan qualified under section 401(a), 403(a), 403(b) or 457 need not demonstrate that all of these requirements will be met with respect to any individual retirement accounts maintained by that governmental unit pursuant to section 408(q). For example, a governmental unit need not demonstrate that it satisfies the net worth requirements of paragraph (e)(3)(ii) of this section if it demonstrates instead that it possesses taxing authority under applicable law. The Commissioner, in his discretion, may exempt a governmental unit from certain other requirements upon a showing that the governmental unit is able to administer the deemed IRAs in the best interest of the participants. Moreover, in determining whether a governmental unit satisfies the other requirements of paragraphs (e)(2) through (e)(6) of this section, the Commissioner may apply the requirements in a manner that is consistent with the applicant's status as a governmental unit.

(ii) *Governmental unit.* For purposes of this special rule, the term *governmental unit* means a state, political subdivision of a state, and any agency or instrumentality of a state or political subdivision of a state.

(iii) *Additional rules.* The Commissioner may in revenue rulings, notices, or other guidance of general applicability provide additional rules for governmental units seeking approval as nonbank trustees.

(iv) *Effective/applicability date.* This section is applicable for written applications made on or after June 18, 2007. The rules in this section also may be relied on for applications submitted on or after August 1, 2003 (or such earlier application as the Commissioner

deems appropriate) and before June 18, 2007.

§ 1.408–2T [Removed]

■ **Par. 3.** Section 1.408–2T is removed.

Kevin M. Brown,
Deputy Commissioner for Services and Enforcement.

Approved:

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E7–11636 Filed 6–15–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 07–025]

RIN 1625-AA00

Safety Zone; BART Transbay Tube Seismic Upgrade; San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a moving temporary safety zone in the navigable waters of San Francisco Bay, California, during geotechnical borings for a seismic upgrade of the Bay Area Rapid Transit (BART) Transbay tube. The borings will require placement of a drilling vessel at test sites along the BART Transbay tube. The safety zone will surround the vessel and move with the vessel as it conducts the tests at eighteen sites along the BART Transbay tube. This safety zone is necessary to protect persons and vessels from hazards, injury, and damage associated with the geotechnical borings. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from May 30, 2007 through June 25, 2007.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket COTP San Francisco Bay 07–025 and are available for inspection or copying at the Waterways Safety Branch of Sector San Francisco, Yerba Buena Island, Bldg. 278, San Francisco, California 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:
Ensign Erin Bastick, U.S. Coast Guard