Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the subcutaneous administration of this oxytetracycline injectable solution to cattle, and for its use in lactating dairy cattle. The supplemental application is approved as of April 8, 2002, and the regulations are amended in 21 CFR 522.1660d 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 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 Dockets Management Branch (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 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.

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) in the second sentence by numerically adding ''011722,''; in the eighth sentence by removing ''011722,''; and in the ninth sentence by removing ''sponsor 000069'' and by adding in its place ''sponsors 000069 and 011722''.

Dated: July 11, 2002.

Andrew J. Beaulieu,

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

[FR Doc. 02–18178 Filed 7–18–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9004]

RIN 1545–AW98

Real Estate Mortgage Investment Conduits

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to safe harbor transfers of noneconomic residual interests in real estate mortgage investment conduits (REMICs). The final regulations provide additional limitations on the circumstances under which transferors may claim safe harbor treatment.

DATES: *Effective Date:* These regulations are effective July 19, 2002.

Applicability Date: For dates of applicability, *see* § 1.860E–(1)(c)(10).

FOR FURTHER INFORMATION CONTACT: Courtney Shepardson at (202) 622–3940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information in this final rule has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507 and assigned control number 1545–1675.

The collection of information in this regulation is in § 1.860E–1(c)(5)(ii). This information is required to enable the IRS to verify that a taxpayer is complying with the conditions of this regulation. The collection of information is mandatory and is required. Otherwise, the taxpayer will not receive the benefit of safe harbor treatment as provided in the regulation. The likely respondents are businesses and other for-profit institutions.

Comments on the collection of information should be sent 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, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:FP:S, Washington, DC 20224. Comments on the collection of information should be received by September 17, 2002. Comments are specifically requested concerning:

Whether the collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

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 total annual reporting burden is 470 hours, based on an estimated number of respondents of 470 and an estimated average annual burden hours per respondent of one hour.

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 final regulations regarding the proposed amendments to 26 CFR part 1 under section 860E of the Internal Revenue Code (Code). The regulations provide the circumstances under which a transferor of a noneconomic REMIC residual interest meeting the investigation and representation requirements may avail itself of the safe harbor by satisfying either the formula test or the asset test.

Final regulations governing REMICs, issued in 1992, contain rules governing the transfer of noneconomic REMIC residual interests. In general, a transfer of a noneconomic residual interest is disregarded for all tax purposes if a significant purpose of the transfer is to

enable the transferor to impede the assessment or collection of tax. A purpose to impede the assessment or collection of tax (a wrongful purpose) exists if the transferor, at the time of the transfer, either knew or should have known that the transferee would be unwilling or unable to pay taxes due on its share of the REMIC's taxable income.

Under a safe harbor, the transferor of a REMIC noneconomic residual interest is presumed not to have a wrongful purpose if two requirements are satisfied: (1) the transferor conducts a reasonable investigation of the transferee's financial condition (the investigation requirement); and (2) the transferor secures a representation from the transferee to the effect that the transferee understands the tax obligations associated with holding a residual interest and intends to pay those taxes (the representation requirement).

The IRS and Treasury have been concerned that some transferors of noneconomic residual interests claim they satisfy the safe harbor even in situations where the economics of the transfer clearly indicate the transferee is unwilling or unable to pay the tax associated with holding the interest. For this reason, on February 7, 2000, the IRS published in the **Federal Register** (65 FR 5807) a notice of proposed rulemaking (REG–100276–97; REG–122450–98) designed to clarify the safe harbor by adding the ''formula test,'' an economic test. The proposed regulation provides that the safe harbor is unavailable unless the present value of the anticipated tax liabilities associated with holding the residual interest does not exceed the sum of: (1) The present value of any consideration given to the transferee to acquire the interest; (2) the present value of the expected future distributions on the interest; and (3) the present value of the anticipated tax savings associated with holding the interest as the REMIC generates losses.

The notice of proposed rulemaking also contained rules for FASITs. Section 1.860H–6(g) of the proposed regulations provides requirements for transfers of FASIT ownership interests and adopts a safe harbor by reference to the safe harbor provisions of the REMIC regulations.

In January 2001, the IRS published Rev. Proc. 2001–12 (2001–3 I.R.B. 335) to set forth an alternative safe harbor that taxpayers could use while the IRS and the Treasury considered comments on the proposed regulations. Under the alternative safe harbor, if a transferor meets the investigation requirement and the representation requirement but the transfer fails to meet the formula test, the transferor may invoke the safe harbor if the transferee meets a two-prong test (the asset test). A transferee generally meets the first prong of this test if, at the time of the transfer, and in each of the two years preceding the year of transfer, the transferee's gross assets exceed $100 million and its net assets exceed $10 million. A transferee generally meets the second prong of this test if it is a domestic, taxable corporation and agrees in writing not to transfer the interest to any person other than another domestic, taxable corporation that also satisfies the requirements of the asset test. A transferor cannot rely on the asset test if the transferor knows, or has reason to know, that the transferee will not comply with its written agreement to limit the restrictions on subsequent transfers of the residual interest.

Rev. Proc. 2001–12 provides that the asset test fails to be satisfied in the case of a transfer or assignment of a noneconomic residual interest to a foreign branch of an otherwise eligible transferee. If such a transfer or assignment were permitted, a corporate taxpayer might seek to claim that the provisions of an applicable income tax treaty would resource excess inclusion income as foreign source income, and that, as a consequence, any U.S. tax liability attributable to the excess inclusion income could be offset by foreign tax credits. Such a claim would impede the assessment or collection of U.S. tax on excess inclusion income, contrary to the congressional purpose of assuring that such income will be taxable in all events. *See,* e.g., sections 860E(a)(1), (b), (e) and 860G(b) of the Code.

The Treasury and the IRS have learned that certain taxpayers transferring noneconomic residual interests to foreign branches have attempted to rely on the formula test to obtain safe harbor treatment in an effort to impede the assessment or collection of U.S. tax on excess inclusion income. Accordingly, the final regulations provide that if a noneconomic residual interest is transferred to a foreign permanent establishment or fixed base of a U.S. taxpayer, the transfer is not eligible for safe harbor treatment under either the asset test or the formula test. The final regulations also require a transferee to represent that it will not cause income from the noneconomic residual interest to be attributable to a foreign permanent establishment or fixed base.

Section 1.860E–1(c)(8) provides computational rules that a taxpayer may use to qualify for safe harbor status under the formula test. Section 1.860E–1(c)(8)(i) provides that the transferee is presumed to pay tax at a rate equal to the highest rate of tax specified in section 11(b). Some commentators were concerned that this presumed rate of taxation was too high because it does not take into consideration taxpayers subject to the alternative minimum tax rate. In light of the comments received, this provision has been amended in the final regulations to allow certain transferees that compute their taxable income using the alternative minimum tax rate to use the alternative minimum tax rate applicable to corporations.

Additionally, § 1.860E–1(c)(8)(iii) provides that the present values in the formula test are to be computed using a discount rate equal to the applicable Federal short-term rate prescribed by section 1274(d). This is a change from the proposed regulation and Rev. Proc. 2001–12. In those publications the provision stated that ''present values are computed using a discount rate equal to the applicable Federal rate prescribed in section 1274(d) compounded semiannually'' and that ''[a] lower discount rate may be used if the transferee can demonstrate that it regularly borrows, in the course of its trade or business, substantial funds at such lower rate from an unrelated third party.'' The IRS and the Treasury Department have learned that, based on this provision, certain taxpayers have been attempting to use unrealistically low or zero interest rates to satisfy the formula test, frustrating the intent of the test. Furthermore, the Treasury Department and the IRS believe that a rule allowing for a rate other than a rate based on an objective index would add unnecessary complexity to the safe harbor. As a result, the rule in the proposed regulations that permits a transferee to use a lower discount rate, if the transferee can demonstrate that it regularly borrows substantial funds at such lower rate, is not included in the final regulations; and the Federal short-term rate has been substituted for the applicable Federal rate. To simplify taxpayers' computations, the final regulations allow use of any of the published short-term rates, provided that the present values are computed with a corresponding period of compounding. With the exception of the provisions relating to transfers to foreign branches, these changes generally have the proposed applicability date of February 4, 2000, but taxpayers may choose to apply the interest rate formula set forth in the proposed regulation and Rev. Proc. 2001–12 for transfers occurring before August 19, 2002.

It is anticipated that when final regulations are adopted with respect to

FASITs, § 1.860H–6(g) of the proposed regulations will be adopted in substantially its present form, with the result that the final regulations contained in this document will also govern transfers of FASIT ownership interests with substantially the same applicability date as is contained in this document.

Effect on Other Documents

Rev. Proc. 2001–12 (2001–3 I.R.B. 335) is obsolete for transfers of noneconomic residual interests in REMICs occurring on or after August 19, 2002.

Special Analyses

It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that it is unlikely that a substantial number of small entities will hold REMIC residual interests. Therefore, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. 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 sections 553(b) and 553(d) of the Administrative Procedure Act (5 U.S.C. chapter 5) do not apply to these regulations.

Drafting Information

The principal author of these regulations is Courtney Shepardson. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and record keeping requirements.

26 CFR Part 602

Reporting and record keeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are 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. In § 1.860A–0, entries in the outline for § 1.860E–1(c)(5) through (c)(10) are added to read as follows:

§ 1.860A–0 Outline of REMIC provisions.

* * * * *

§ 1.860E–1 Treatment of taxable income of a residual interest holder in excess of daily accruals.

* * * * *

(c) * * *

(5) Asset test.

(6) Definitions for asset test.

(7) Formula test.

(8) Conditions and limitations on formula test.

(9) Examples.

(10) Effective dates.

* * * * *

Par. 3. Section 1.860E–1 is amended as follows:

1. Paragraph (c)(4)(i) is amended by removing the language ''and'' at the end of the paragraph.

2. Paragraph (c)(4)(ii) is amended by removing the period at the end of the paragraph and adding a semicolon in its place.

3. Paragraphs (c)(4)(iii) and (c)(4)(iv) are added.

4. Paragraphs (c)(5) through (c)(10) are added.

The additions read as follows:

§ 1.860E–1 Treatment of taxable income of a residual interest holder in excess of daily accruals.

* * * * *

(c) * * *

(4) * * *

(iii) The transferee represents that it will not cause income from the noneconomic residual interest to be attributable to a foreign permanent establishment or fixed base (within the meaning of an applicable income tax treaty) of the transferee or another U.S. taxpayer; and

(iv) The transfer satisfies either the asset test in paragraph (c)(5) of this section or the formula test in paragraph (c)(7) of this section.

(5) *Asset test.* The transfer satisfies the asset test if it meets the requirements of paragraphs (c)(5)(i), (ii) and (iii) of this section.

(i) At the time of the transfer, and at the close of each of the transferee's two fiscal years preceding the transferee's fiscal year of transfer, the transferee's gross assets for financial reporting purposes exceed $100 million and its net assets for financial reporting purposes exceed $10 million. For purposes of the preceding sentence, the gross assets and net assets of a transferee do not include any obligation of any related person (as defined in paragraph (c)(6)(ii) of this section) or any other asset if a principal purpose for holding or acquiring the other asset is to permit the transferee to satisfy the conditions of this paragraph (c)(5)(i).

(ii) The transferee must be an eligible corporation (defined in paragraph (c)(6)(i) of this section) and must agree in writing that any subsequent transfer of the interest will be to another eligible corporation in a transaction that satisfies paragraphs (c)(4)(i), (ii), and (iii) and this paragraph (c)(5). The direct or indirect transfer of the residual interest to a foreign permanent establishment (within the meaning of an applicable income tax treaty) of a domestic corporation is a transfer that is not a transfer to an eligible corporation. A transfer also fails to meet the requirements of this paragraph (c)(5)(ii) if the transferor knows, or has reason to know, that the transferee will not honor the restrictions on subsequent transfers of the residual interest.

(iii) A reasonable person would not conclude, based on the facts and circumstances known to the transferor on or before the date of the transfer, that the taxes associated with the residual interest will not be paid. The consideration given to the transferee to acquire the noneconomic residual interest in the REMIC is only one factor to be considered, but the transferor will be deemed to know that the transferee cannot or will not pay if the amount of consideration is so low compared to the liabilities assumed that a reasonable person would conclude that the taxes associated with holding the residual interest will not be paid. In determining whether the amount of consideration is too low, the specific terms of the formula test in paragraph (c)(7) of this section need not be used.

(6) *Definitions for asset test.* The following definitions apply for purposes of paragraph (c)(5) of this section:

(i) *Eligible corporation* means any domestic C corporation (as defined in section 1361(a)(2)) other than—

(A) A corporation which is exempt from, or is not subject to, tax under section 11;

(B) An entity described in section 851(a) or 856(a);

(C) A REMIC; or

(D) An organization to which part I of subchapter T of chapter 1 of subtitle A of the Internal Revenue Code applies.

(ii) *Related person* is any person that—

(A) Bears a relationship to the transferee enumerated in section 267(b) or 707(b)(1), using ''20 percent'' instead of ''50 percent'' where it appears under the provisions; or

(B) Is under common control (within the meaning of section 52(a) and (b)) with the transferee.

(7) *Formula test.* The transfer satisfies the formula test if the present value of the anticipated tax liabilities associated

with holding the residual interest does not exceed the sum of—

(i) The present value of any consideration given to the transferee to acquire the interest;

(ii) The present value of the expected future distributions on the interest; and

(iii) The present value of the anticipated tax savings associated with holding the interest as the REMIC generates losses.

(8) *Conditions and limitations on formula test.* The following rules apply for purposes of the formula test in paragraph (c)(7) of this section.

(i) The transferee is assumed to pay tax at a rate equal to the highest rate of tax specified in section 11(b)(1). If the transferee has been subject to the alternative minimum tax under section 55 in the preceding two years and will compute its taxable income in the current taxable year using the alternative minimum tax rate, then the tax rate specified in section 55(b)(1)(B) may be used in lieu of the highest rate specified in section 11(b)(1).

(ii) The direct or indirect transfer of the residual interest to a foreign permanent establishment or fixed base (within the meaning of an applicable income tax treaty) of a domestic transferee is not eligible for the formula test.

(iii) Present values are computed using a discount rate equal to the Federal short-term rate prescribed by section 1274(d) for the month of the transfer and the compounding period used by the taxpayer.

(9) *Examples.* The following examples illustrate the rules of this section:

Example 1. Transfer to partnership. X transfers a noneconomic residual interest in a REMIC to Partnership *P* in a transaction that does not satisfy the formula test of paragraph (c)(7) of this section. *Y* and *Z* are the partners of *P*. Even if *Y* and *Z* are eligible corporations that satisfy the requirements of paragraph (c)(5)(i) of this section, the transfer fails to satisfy the asset test requirements found in paragraph (c)(5)(ii) of this section because *P* is a partnership rather than an eligible corporation within the meaning of (c)(6)(i) of this section.

Example 2. Transfer to a corporation without capacity to carry additional residual interests. During the first ten months of a year, Bank transfers five residual interests to Corporation *U* under circumstances meeting the requirements of the asset test in paragraph (c)(5) of this section. Bank is the major creditor of *U* and consequently has access to *U*'s financial records and has knowledge of *U*'s financial circumstances. During the last month of the year, Bank transfers three additional residual interests to *U* in a transaction that does not meet the formula test of paragraph (c)(7) of this section. At the time of this transfer, *U*'s financial records indicate it has retained the previously transferred residual interests. *U*'s financial circumstances, including the aggregate tax liabilities it has assumed with respect to REMIC residual interests, would cause a reasonable person to conclude that *U* will be unable to meet its tax liabilities when due. The transfers in the last month of the year fail to satisfy the investigation requirement in paragraph (c)(4)(i) of this section and the asset test requirement of paragraph (c)(5)(iii) of this section because Bank has reason to know that *U* will not be able to pay the tax due on those interests.

Example 3. Transfer to a foreign permanent establishment of an eligible corporation. R transfers a noneconomic residual interest in a REMIC to the foreign permanent establishment of Corporation *T*. Solely because of paragraph (c)(8)(ii) of this section, the transfer does not satisfy the formula test of paragraph (c)(7) of this section. In addition, even if *T* is an eligible corporation, the transfer does not satisfy the asset test because the transfer fails the requirements of paragraph (c)(5)(ii) of this section.

(10) *Effective dates.* Paragraphs (c)(4) through (c)(9) of this section are applicable to transfers occurring on or after February 4, 2000, except for paragraphs (c)(4)(iii) and (c)(8)(iii) of this section, which are applicable for transfers occurring on or after August 19, 2002. For the dates of applicability of paragraphs (a) through (c)(3) and (d) of this section, see § 1.860A–1.

* * * * *

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 5. In § 602.101, paragraph (b) is amended by adding an entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.860E–1	1545–1675
* * * * *	

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: July 10, 2002

Pamela F. Olson,

Acting Assistant Secretary of the Treasury.

[FR Doc. 02–18021 Filed 7–18–02; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 601

[TD 9006]

RIN 1545–AY68

Notice to Interested Parties

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the notice to interested parties requirement. Before the IRS can issue an advance determination regarding the qualification of a retirement plan, a plan sponsor must provide evidence that it has notified all persons who qualify as interested parties that an application for an advance determination will be filed with the IRS. These regulations set forth standards by which a plan sponsor may satisfy the notice to interested parties requirement. The final regulations affect retirement plan sponsors, plan participants and other interested parties with respect to a determination letter application, and certain representatives of interested parties.

DATES: Effective Date: These regulations are effective on July 19, 2002.

Applicability Date: These regulations apply to applications made on or after January 1, 2003.

FOR FURTHER INFORMATION CONTACT: Pamela R. Kinard, (202) 622–6060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to 26 CFR parts 1 and 601 under section 7476 of the Internal Revenue Code of 1986 (Code). On May 21, 1976, final regulations (TD 7421) under section 7476 were published in the **Federal Register** (41 FR 20874). These final regulations provide guidance on the nature and method of giving notice to interested parties. On January 17, 2001, a notice of proposed rulemaking (REG–129608–00) was published in the **Federal Register** (66 FR 3954), setting forth the proposed new standards for delivery of the notice to interested