

(21) Payments made to individuals who were captured and interned by the Democratic Republic of Vietnam as a result of participation in certain military operations, pursuant to section 606 of Public Law 105-78 and section 657 of Public Law 104-201 (110 Stat. 2584).

(22) Payments made to certain Vietnam veterans' children with spina bifida, pursuant to section 421 of Public Law 104-204 (38 U.S.C. 1805(d)).

(23) Payments made to the children of women Vietnam veterans who suffer from certain birth defects, pursuant to section 401 of Public Law 106-419, (38 U.S.C. 1833(c)).

(24) For the 9 months following the month of receipt, any unspent portion of any refund of Federal income taxes under section 24 of the Internal Revenue Code of 1986 (relating to the child care tax credit), pursuant to section 431 of Public Law 108-203 (118 Stat. 539).

■ 12. Section 416.1248 is added to read as follows:

**§ 416.1248 Exclusion of gifts to children with life-threatening conditions.**

In determining the resources of an individual who has not attained 18 years of age and who has a life-threatening condition, we will exclude any gifts from an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 which is exempt from taxation under section 501(a) of such Code. We will exclude any in-kind gift that is not converted to cash and cash gifts to the extent that the total gifts excluded pursuant to this paragraph do not exceed \$2000 in any calendar year. In-kind gifts converted to cash are considered under income counting rules in the month of conversion.

■ 13. Section 416.1249 is added to read as follows:

**§ 416.1249 Exclusion of payments received as restitution for misuse of benefits by a representative payee.**

In determining the resources of an individual (and spouse, if any), the unspent portion of any payment received by the individual as restitution for title II, title VIII or title XVI benefits misused by a representative payee under § 404.2041, § 408.641 or § 416.641, respectively, is excluded for 9 months following the month of receipt.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 520 and 529

#### Certain Other Dosage Form New Animal Drugs; Oxytetracycline

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

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

**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 Pfizer, Inc. The supplemental NADA provides for use of oxytetracycline hydrochloride soluble powder for skeletal marking of finfish fry and fingerlings by immersion. **DATES:** This rule is effective July 18, 2005.

**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.gov.

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017-5755, filed a supplement to NADA 8-622 that provides for use of TERRAMYCIN-343 (oxytetracycline HCl) Soluble Powder for skeletal marking of finfish fry and fingerlings by immersion. The approval of this supplemental NADA relied on publicly available safety and effectiveness data contained in Public Master File (PMF) 5667 which were compiled under National Research Support Project-7 (NRSP-7), a national agricultural research program for obtaining clearances for use of new drugs in minor animal species and for special uses. In addition, the supplemental NADA provides for the addition of statements to product labeling warning against the use of this product in drinking water of lactating dairy cattle. The supplemental NADA is approved as of June 13, 2005, and the regulations in 21 CFR 529.1660 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, FDA has found that the regulations contain incorrect statements warning against the use of oxytetracycline soluble powder in calves intended for veal. Accordingly, the regulations in 21 CFR 520.1660d are amended to reflect appropriate warning statements for this product. This action is 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.

FDA has determined under 21 CFR 25.33(d)(4) 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 Parts 520 and 529

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 520 and 529 are 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.

■ 2. Section 520.1660d is amended by revising paragraph (d)(1)(iv)(C) to read as follows:

#### § 520.1660d Oxytetracycline hydrochloride soluble powder.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(iv) \* \* \*

(C) *Limitations.* Prepare a fresh solution daily. Administer up to 14 days. Do not use for more than 14 consecutive days. Use as sole source of oxytetracycline. Do not administer this product with milk or milk replacers. Administer 1 hour before or 2 hours after feeding milk or milk replacers. Withdraw 5 days prior to slaughter. A milk discard period has not been established for this product in lactating dairy cattle. Do not use in female dairy cattle 20 months of age or older.

\* \* \* \* \*

**PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

■ 3. The authority citation for 21 CFR part 529 continues to read as follows:

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

**§ 529.1660 [Amended]**

■ 4. Section 529.1660 is amended in paragraph (b)(2) by removing “No. 059130” and by adding in its place “Nos. 000069 and 059130”.

Dated: July 1, 2005.

Catherine P. Beck,

Acting Director, Center for Veterinary Medicine.

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 26**

[TD 9214]

RIN 1545–BC60

**Predeceased Parent Rule**

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

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations relating to the predeceased parent rule, which provides an exception to the general rules of section 2651 of the Internal Revenue Code (Code) for determining the generation assignment of a transferee of property for generation-skipping transfer (GST) tax purposes. These regulations also provide rules regarding a transferee assigned to more than one generation. The regulations reflect changes to the law made by the Taxpayer Relief Act of 1997 and generally apply to individuals, trusts, and estates.

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

**FOR FURTHER INFORMATION CONTACT:** Lian A. Mito at (202) 622–7830 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Background**

On September 3, 2004, a notice of proposed rulemaking (REG–145988–03) relating to the predeceased parent rule was published in the **Federal Register** (69 FR 53862). The public hearing scheduled for December 14, 2004, was cancelled because no requests to speak were received. Written comments responding to the notice of proposed rulemaking were received. After

consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision. The revisions are discussed below.

**Summary of Comments**

The proposed regulations provided that, for purposes of determining whether the predeceased parent rule applies, an individual transferee's interest in property is established or derived at the time the transferor who transferred the property is subject to either the gift or estate tax on the property. If the transferor will be subject to a transfer tax imposed on the property transferred on more than one occasion, then the relevant time for determining whether the predeceased parent rule applies is the earliest time at which the transferor is subject to the gift or estate tax. In the case of a trust for which an election under section 2056(b)(7) (QTIP election) has been made, the proposed regulations provided that the interest of the remainder beneficiary is considered as established or derived when the QTIP trust was established. However, the proposed regulations also included an exception to this general rule by providing that, to the extent of the QTIP (but not a reverse QTIP) election, the remainder beneficiary's interest is deemed to have been established or derived on the death of the transferor's spouse (the income beneficiary), rather than on the transferor's earlier death.

One commentator indicated that this exception is unnecessary. The commentator believes that the proposed regulations misinterpreted the statute because a remainder beneficiary's interest in a trust that is subject to a QTIP (but not a reverse QTIP) election should always be deemed to have been established, not at the time of the trust's creation, but rather at the time when the income-beneficiary spouse is first subject to gift or estate tax on the trust property. This position applies the definition of “transferor” in section 2652 in the context of the reference to “established and derived” in section 2651(e), and is based on the conclusion that the tax in this situation is not imposed on the same transferor on more than one occasion. Thus, because the donee or surviving spouse becomes the transferor of a trust that is subject to a QTIP (but not reverse QTIP) election, the remainder beneficiary's interest in such a trust is established upon that spouse's gift of an interest in the trust or that spouse's death, in each case the time at which gift or estate tax on the trust is first imposed on that spouse. Viewed from this perspective, this provision of the proposed regulations is

not an exception. The Treasury Department and the IRS agree, and the final regulations adopt the suggested change.

Under the proposed regulations, the predeceased parent rule does not apply to transfers to collateral heirs if, at the time of the transfer, “the transferor (or the transferor's spouse or former spouse) has any living lineal descendant.” Thus, under the proposed regulations, if, at the time of the transfer, the transferor has no living lineal descendants but the transferor's spouse or former spouse does, the predeceased parent rule will not apply to any transfer by the transferor to a collateral heir. A number of commentators pointed out that the parenthetical language is inconsistent with the purpose and language of the statute, and will inappropriately narrow the application of the predeceased parent rule with respect to collateral heirs. The Treasury Department and the IRS agree, and the parenthetical language is removed in the final regulations. Accordingly, the final regulations require that, for the predeceased parent rule to apply to transfers to collateral heirs, only the transferor must have no living lineal descendants at the time of the transfer.

The proposed regulations provided an exception to the general rule that assigns an individual to the youngest of the generations to which that individual may be assigned. Under the exception, an adopted individual will be treated as a member of the generation that is one generation below the adoptive parent for purposes of determining whether a transfer to the adopted individual from the adoptive parent (or the spouse or former spouse of the adoptive parent, or a lineal descendant of a grandparent of the adoptive parent) is subject to the GST tax. The proposed regulations defined an “adopted individual” as an individual who is: (1) A descendant of a parent of the adoptive parent (or the spouse or former spouse of the adoptive parent); and (2) under the age of 18 at the time of the adoption.

Two commentators expressed concern that this objective test (specifically, the age at the time of the adoption) provides a strong inducement to engage in a tax-motivated adoption, particularly in the case of older minors, because of the amount of GST tax that thereby may be avoided. One commentator suggested lowering the limit on the age of the individual at the time of the adoption for purposes of the test. The other commentator recommended adding a third element to the definition of adopted individual, namely, that the individual was not adopted primarily for tax-avoidance purposes.