and swine. The supplemental ANADA provides for the subcutaneous administration of OTC injectable solution in beef cattle, nonlactating dairy cattle, and calves, including preruminating (veal) calves. The supplemental application is approved as of December 28, 2001, and the regulations are amended in 21 CFR 522.1660 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 supplemental 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 Subjects 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:

§ 522.1660 [Amended]

2. Section 522.1660 Oxytetracycline injection is amended in the second sentence in paragraph (d)(1)(iii) by removing “Sponsors 000010 and 053389,” and adding in its place “Sponsors 000010, 053389, and 059130”.

Claire M. Lathers,  
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.  

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 53, 301, and 602

TD 8987

RIN 1545–AY65

Excise Taxes on Excess Benefit Transactions; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to final regulations.

SUMMARY: This document contains corrections to final regulations that were published in the Federal Register on Wednesday, January 23, 2002 (67 FR 3076) relating to the excess taxes on excess benefit transactions.

DATES: This correction is effective January 23, 2002.

FOR FURTHER INFORMATION CONTACT: Phyllis D. Haney, (202) 622–4290 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections are under section 4958 of the Internal Revenue Code.

Need for Correction

As published, the final regulations contain errors that may prove to be misleading and are in need of clarification.

Correction of Publication

Accordingly, the publication of the final regulations (TD 8978), that were the subject of FR Doc. 02–985, is corrected as follows:

1. On page 3078, column 1, in the preamble under the paragraph heading “Definition of Applicable Tax-Exempt Organization”, line 6 from the top of the column, the language “to the efficient administration of the” is corrected to read “for the efficient administration of the”.

2. On page 3082, column 3, in the preamble under the paragraph heading “Final Regulatory Flexibility Analysis”, first paragraph, line 13, the language “REP. 104–506 at 56–7, March 28, 1996)” is corrected to read “REP. 506, 104th Congress, 2d SESS. (1996), 53, 56–7)”.

3. On page 3083, column 1, in the preamble under the paragraph heading “Final Regulatory Flexibility Analysis”, first full paragraph, line 1, the language “The objective for the rebuttable” is corrected to read “The objective of the rebuttable”.


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§ 53.4958–4 [Corrected]
4. On page 3091, column 3, § 53.4958–4(a)(3)(vii), Example 1, line 12, the language “T (see § 53.4958–3(a)). Under the initial” is corrected to read “T (see § 53.4958–3(c)(3)). Under the initial”.
5. On page 3095, column 2, § 53.4958–4(c)(4), Example 2, line 10, the language “D fails to report the bonus on his individual” is corrected to read “D fails to report the bonus on D’s individual”.

§ 301.7611–1 [Corrected]
6. On page 3099, column 2, in A–19, line 1, the language “A–19: See § 53.4958–7(b) of this” is corrected to read “A–19: See § 53.4958–8(b) of this”.

Cynthia E. Grigsby,
Chief, Regulations Unit, Associate Chief Counsel, (Income Tax and Accounting).

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DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA62

Civilian-Health and Medical Program of the Uniformed Services (CHAMPUS); Partial Implementation of Pharmacy Benefits Program; Implementation of National Defense Authorization Act for Fiscal Year 2001

AGENCY: Office of the Secretary, Department of Defense.

ACTION: Interim final rule; administrative corrections.

SUMMARY: On October 23, 2000 (65 FR 63202), the Department of Defense published a final rule concerning the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) TRICARE Dental Program. This document is published to correct an administrative error in those rules for the Uniformed Services (CHAMPUS) Civilian Health and Medical Program of the Department of Defense also published an interim final rule concerning, among other issues, partial implementation of the Pharmacy Benefits Program and amended 32 CFR part 199 by adding a new section 199.21, Pharmacy Benefits Program to replace the previously reserved section 199.21. On February 15, 2001 (66 FR 10367) and March 26, 2001 (66 FR 16400), DoD published corrections to the interim final rule changing the effective date to April 1, 2001, and making other administrative changes. Unfortunately, republication of the TRICARE Dental Program final rule on March 1, 2001, amending 32 CFR part 199 to remove section 199.21 (thereby intending to remove section 199.21, TRICARE Selected Reserve Dental Program, as stated in the Supplemental Information section of the final rule) resulted in a technical error removing section 199.21, Pharmacy Benefits Program which was added by the Pharmacy Benefits Program interim final rule to become effective April 1, 2001.

List of Subjects in 32 CFR Part 199

Claims, Dental health, Health care, Health insurance, Individuals with disabilities, Military personnel. Accordingly, 32 CFR part 199 is amended as follows:

1. The authority citation continues to read as follows:


2. Section 199.21 is added to read as follows:

§ 199.21 Pharmacy Benefits Program.
(a) In general.—(1) Statutory authority. 10 U.S.C. 1074g requires that the Department of Defense establish an effective, efficient, integrated Pharmacy Benefits Program for the Military Health System. This law is independent of a number of section of title 10 and other laws that affect the benefits, rules, and procedures of CHAMPUS/TRICARE, resulting in changes to the rules otherwise applicable to TRICARE Prime, Standard, and Extra. Among these changes is an independent set of beneficiary co-payments for prescription drugs.

(2) Partial implementation during interim period. Beginning April 1, 2001, 10 U.S.C. 1074g is partially implemented to coincide with the start of the TRICARE Senior Pharmacy Program and substantial cost sharing changes for active duty dependents enrolled in Prime. Some authorities and requirements of Section 1074g, such as the classification of drugs as formulary or non-formulary under a “uniform formulary of pharmaceutical agents,” are not yet implemented. In this section, references to “interim implementation period” mean the period beginning April 1, 2001.

(b) Program benefits. During the interim implementation period, prescription drugs and medicines are available under the otherwise applicable rules and procedures for military treatment facility pharmacies, TRICARE Prime, Standard, and Extra, and the Mail Order Pharmacy Program. There is not during this interim implementation period a “uniform formulary” of drugs and medicines available in all of these parts of the system. All cost sharing requirements for prescription drugs and medicines are established in this section for pharmacy services provided throughout the Military Health System.

(c) Providers of pharmacy services. There are four categories of providers of pharmacy services: military treatment facilities (MTFs), network retail providers, non-network retail providers, and the mail service pharmacy program. Network retail providers are those non-MTF pharmacies that are a part of the network established for TRICARE Prime under § 199.17. Non-network pharmacies are those non-MTF pharmacies that are not part of such a network.

(d) Classifications of drugs and medicines. During the interim implementation period, a distinction is made for purposes of cost sharing between generic drugs and non-generic (or brand name) drugs.

(e) TRICARE Senior Pharmacy Program. Section 711 of the Floyd D. Spence National Defense Authorization Act for Fiscal Year 2001 (Public Law 106–398, 114 Stat. 1654) established the TRICARE Senior Pharmacy Program for Medicare eligible beneficiaries effective April 1, 2001. These beneficiaries are required to meet the eligibility criteria as prescribed in § 199.3. The benefit under the TRICARE Senior Pharmacy Program includes the Basic Program pharmacy benefits as found under § 199.4(d) and the pharmacy benefit and cost sharing as found under this part. The TRICARE Senior Pharmacy Program applies to prescription drugs and medicines provided on or after April 1, 2001.

(f) Cost sharing. Beneficiary cost sharing requirements for prescription drugs and medicines are based upon the generic/non-generic status and the point...